



Blue Bell Creameries, Inc.
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May 22, 2015

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

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

Dear Mr. Rodriguez,

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 483s) issued to our ice cream processing facilities in Brenham, Texas, and Broken Arrow, Oklahoma. We are responding separately to the New Orleans District regarding the FDA Form 483 issued to our facility in Sylacauga, Alabama.

Producing safe, wholesome products for our consumers to enjoy is Blue Bell's highest priority, and we are taking this situation very, very seriously. Since the initial recall, we have consistently sought to make the right decisions based on the best available evidence and in full cooperation with FDA and our state regulators. We conducted multiple recalls based on the most recently available test results, culminating in a recall of all of our products so we can be certain consumers are safe. 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.

We have assembled a team with deep expertise in food safety to help us address these issues. (b) (4) (b) (4) and a team of expert scientific consultants are working with the Company in thoroughly analyzing all aspects of our facilities and our operations. Our entire company has been hard at work thoroughly cleaning and sanitizing our equipment, drains, and our facilities to control for *Listeria*. And we are critically reviewing and revising all of our processes and procedures, as needed, to ensure this does not happen again. We have addressed each Observation on the 483s, but we have also taken a holistic approach to comprehensively evaluating all aspects of our operations.

Mr. Reynaldo Rodriguez
U.S. Food and Drug Administration
May 22, 2015
Page 2

Throughout this process, we have sought to work closely with FDA and our state regulators, and we have appreciated the open, cooperative, and professional working relationship with FDA. We firmly believe that this cooperative relationship led to better information exchange, better decision-making, and ultimately better protection of public health. We remain firmly committed to a transparent and open relationship with FDA as we implement corrective and preventive actions. As FDA is aware, we have entered into voluntary agreements with the states of Texas and Oklahoma (copies attached) clearly spelling out the steps we will take and the conditions we must meet before resuming operations, (b) (4). We make the same commitment to FDA: we will not resume commercial distribution from any of our facilities until both we and FDA are satisfied that we have adequately addressed the *Listeria* issue and are producing safe, wholesome product.

Importantly, we will be taking a consistent approach in each of our facilities. That is, we will be using the same standard operating procedures, testing programs, supplier verification procedures, and overall philosophy in Brenham, Broken Arrow and Sylacauga. These programs and procedures will be tailored to each facility, as needed, based on the facility size and products to be manufactured there. Due to the differing sizes and scope of work needed at the different facilities, we anticipate that the smaller facilities in Broken Arrow and Sylacauga will be ready to resume operations earlier than the main facility in Brenham. At this time, we have deferred remedial action at our Brenham snack facility until we have completed work at our other three facilities.

Consistent with our state voluntary agreements and our responsibilities under the law, we have developed the following action steps to help guide our efforts:

- **Expert Consultants.** We have retained independent microbiological and sanitation experts to assist with our evaluation and corrective actions.
- **Root Cause Analysis.** We are conducting root cause analyses to better understand the sources of *Listeria* and how to eliminate them.
- **Corrective Actions.** We are implementing corrective actions to address all issues identified in FDA and state inspections as well as through our own internal reviews.
- **Deep Cleaning and Sanitation.** We are thoroughly cleaning and sanitizing all areas of our facilities and equipment, disassembling equipment as needed.
- **Employee Training.** We are conducting comprehensive training of all employees on proper procedures, good manufacturing practices (GMPs), and proper hygiene for a food manufacturing facility.
- **Cleaning and Sanitation Programs.** We are reviewing and revising our cleaning and sanitation standard operating procedures (SSOPs) to ensure all surfaces and equipment are clean and sanitized when we start each day's production.

- **Environmental and Product Testing Programs.** We are reviewing and revising our environmental testing program to verify that our cleaning and sanitation programs are operating effectively. Once we resume operations, we intend to implement a finished product test-and-hold program on all of our products for a period (b) (4). We are also developing an appropriate program for testing of incoming ingredients as part of an updated supplier verification program. We will maintain all test results in our files, making them available to FDA and state regulators upon request.
- **Reporting of Product Test Results:** We will voluntarily report to the FDA and to our state regulators any presumptive positive test results for *Listeria monocytogenes* from finished products or ingredients, for a period (b) (4) from the date of initial market reintroduction, even if such reporting is not required under the Reportable Food Registry.
- **Pilot Production Runs.** We will conduct pilot production runs to evaluate our readiness for resuming commercial operations. Such pilot production will be conducted in accordance with our revised SSOPs and our Test-and-Hold program.
- **Regulatory Clearance.** We will notify FDA and state regulators at least 2 weeks prior to reintroducing products into commerce and will await concurrence from all applicable regulators before reintroducing product into commerce. We recognize that FDA and/or our state regulators may wish to inspect and/or take samples as part of this evaluation.

Accordingly, we are moving forward with our remediation efforts in a structured way, and 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 product.

Blue Bell hopes our efforts demonstrate the seriousness with which we are taking this situation as well as our commitment to making sure we get this right. We are committed to seeing this plan through and to working with FDA each step of the way. Once we, FDA, and the applicable state regulators agree we are ready to reintroduce products into commerce, we plan to resume production with a (b) (4) only after our revised programs have demonstrated they are capable of ensuring product safety. At this point in time, we intend our (b) (4) (b) (4) and a (b) (4).

Please find enclosed our responses to each Observation on the 483s, including corrective actions. 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 483s in 60 days, and again in 120 days if needed.

Mr. Reynaldo Rodriguez
U.S. Food and Drug Administration
May 22, 2015
Page 4

We look forward to discussing these plans with you in person and to answering any of your questions. As you know, we are in contact with your office to arrange a date and time for that meeting.

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 Ruth Dixon, Director of the New Orleans District Office to this cover letter, and we will copy you on our companion response to the 483 from the Sylacauga inspection.

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 Ruth Dixon, Director
New Orleans District Office (without attachments)

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

(b) (4)
Counsel to Blue Bell Creameries, Inc.

(b) (4)
Counsel to Blue Bell Creameries, Inc.

Mr. Reynaldo Rodriguez
U.S. Food and Drug Administration
May 22, 2015
Page 5

Enclosures

Tab A: Blue Bell Creameries, Inc., Response to FDA Form 483 Issued to Brenham Facility on May 1, 2015

Tab B: Blue Bell Creameries, Inc., Response to FDA Form 483 Issued to Broken Arrow Facility on April 23, 2015

Tab C: Voluntary Agreement with Texas

Tab D: Voluntary Agreement with Oklahoma

Blue Bell Creameries
Detailed Response to FDA 483

Brenham, Texas

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 Brenham, Texas, facility on May 1, 2015 (the 483) (Attachment 1). We appreciate the professionalism demonstrated by the FDA investigators when they inspected our Brenham facility from March 16, 2015, through May 1, 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 Brenham, Texas. As FDA is aware, on April 20, 2015, based on test results on samples that we collected in our Brenham, Texas, facility and that we shared with FDA, we voluntarily chose to recall all products produced by the Company out of an abundance of caution. On April 20, 2015, we also voluntarily elected to completely suspend all commercial operations at all our ice cream facilities until we were confident we had identified and eliminated the source(s) of all *Listeria monocytogenes* (*Lm*) contamination. After producing product for a week for evaluation only (and slated for subsequent destruction, with a small amount retained for testing), we stopped all production as of close of business April 24, 2015. Throughout this process, we have been working tirelessly to identify and address issues that led to *Lm* contamination in some of our products. 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 fully 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) 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) is (b) (4) (b) (4). He also serves as (b) (4) at the (b) (4) (b) (4) has authored numerous publications on food safety, and lectures and presents widely on the topic. (b) (4) 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), also brings more than three decades of food safety experience. He is (b) (4) for (b) (4). (b) (4) publishes and speaks widely on food safety and has extensive experience with developing food safety programs.
- (b) (4) also has nearly thirty years of food safety experience and is the (b) (6) (b) (4) for (b) (4). (b) (4) 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), has more than thirty years of experience with food safety and microbiology. (b) (4) is (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).

Early actions focused on efforts to identify the potential source(s) of the contamination. *Listeria* is a ubiquitous organism in the environment, and our challenge was to find and eradicate harborage sites in the plant and equipment. Initial efforts included systematically breaking down equipment and lines in a search for a primary harborage site (such as the belt feeder for Area (b) (4) Line (b) (6) the use of belt feeders has been discontinued companywide). It eventually became evident that we would not be able to identify a single source for our entire Brenham facility, so we adopted a broad-focused remediation plan.

In addition to analyzing the source—and as part of our broad-focused remediation efforts—we have worked tirelessly to clean and sanitize throughout our facility, a process facilitated by our decision to completely stop production. We are systematically cleaning and sanitizing all parts of 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.

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 manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms.

Specifically,

The following lots of products, which were manufactured on (b) (4) line (b) (4) between 8/29/14 and 1/21/15 and subsequently distributed into commerce, were sampled by your firm and found positive for *Listeria monocytogenes*.

- Great Divide Bar (Bulk packaging), manufactured on 1/12/15, lot 011217A, and distributed between 1/13/15 - 2/10/15.
- Chocolate Chip Country Cookie (Bulk Packaging), manufactured on 01/20/15, lot 012017A, and distributed between 1/20/15 - 2/11/15.

Additionally, your firm ceased production on 1/30/15, to undergo routine cleaning and overhauling of (b) (4) line (b) (4). On 2/13/15, your firm received notification from DSHS of your products positive for *Listeria monocytogenes*. Prior to resuming operations on this line, your firm swabbed the (b) (4) Line (b) (4) equipment and found the following listeria positive swabs:

- 2/19/15, inside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4)
- 2/21/15, the outside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4)

On 2/23/15, your firm resumed operations on the (b) (4) line (b) (4) continuing to manufacture on 3/2/15, 3/3/15, 3/4/15, 3/5/15, 3/6/15, and 3/9/15. After each of these manufacturing days your firm performed routine cleaning and sanitizing. However, on 3/9/15, your firm found *Listeria monocytogenes* positive swabs in (b) (4) line (b) (4) in the (b) (4) bottom (food contact surface) and in the underside (b) (4) chainsprocket (food contact surface). During 3/9/15, the (b) (4) line (b) (4) was manufacturing Sour Pop Apples (lot# 030917A). However, the Sour Pop Apples (lot # 030917A) were never offered for sale.

Response:

Since the initial recall, we have strived to act responsibly based on the best evidence available at the time, always with the objective of protecting our consumers. We have also worked hard to maintain clear, open communications with FDA, our state regulators, and our customers, recognizing that public health is best protected if we all work together.

We learned on February 13, 2015, that samples of Blue Bell ice cream products produced at the Brenham facility—Great Divide Bar and Chocolate Chip Country Cookie—tested by the State of South Carolina had tested presumptive positive for *Lm*. We submitted a report to the FDA Reportable Food Registry that same day. On February 16, 2015, we made the decision to withdraw from commerce all products produced on the (b) (4) line, which was the line that produced the products in question. On March 9, 2015, we learned of a potential link between illnesses in patients

in a Kansas hospital and a certain product called Scoops prepared on the (b) (4) line in the Brenham facility. After further investigation, we decided on March 10, 2015, to stop running the (b) (4) machine and to discontinue our (b) (4) products until the source of the contamination could be found and eradicated; we have since decided to discontinue use of the (b) (4) machine permanently. We ultimately shut down all production in the second floor room containing the (b) (4) machine, notifying FDA by telephone on March 24 and confirming that in writing by email on March 26. Accordingly, no ice cream was produced on the (b) (4) machine as of close of business March 10, 2015, and no ice cream was produced elsewhere in the second floor room containing the (b) (4) machine as of close of business March 24, 2015.

Observation 2:

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

Specifically,

After shutting down (b) (4) line (b) (4) for cleaning and overhauling (b) (4) line (b) (4) on 1/30/15, your firm received notification from DSHS on 2/13/15 (regarding positive findings of *Listeria monocytogenes* in your products), your firm collected environmental samples of (b) (4) Line (b) (4) and swabs taken at the following two locations were subsequently found positive for *Listeria monocytogenes*:

Swab collected from the inside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4) on 2/19/15.

Swab collected from the outside drain of the freezer tunnel (non-food contact surface) of the (b) (4) line (b) (4) on 2/21/15.

Your firm then resumed manufacturing, cleaning and sanitizing operations for (b) (4) line (b) (4) on 2/23/15, 3/2/15, 3/3/15, 3/4/15, 3/5/15, 3/6/15, and 3/9/15. However, on 3/9/15, your firm found *Listeria monocytogenes* positive swabs in (b) (4) line (b) (4) in the (b) (4) bottom (food contact surface) and in the underside (b) (4) chainsprocket (food contact surface). During 3/9/15, the (b) (4) line (b) (4) was manufacturing Sour Pop Apples (lot# 030917A). However, the Sour Pop Apples (lot # 030917A) were never offered for sale.

Response:

As noted above, we took the findings from the (b) (4) machine very seriously. No ice cream was produced on the (b) (4) machine as of close of business on March 10, 2015, and affected products were withdrawn.

On the more general issue of adequate cleaning and sanitizing, 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 zoned 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) environmental swabs from zones 2–4 (non-food contact surfaces) (b) (4). Samples will be collected (b) (4) (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, (b) (4), using (b) (4) (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 zone 1 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 re-swab the site and will take (b) (4) additional vector swabs from points within a (b) (4) radius 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 vector swabbing until (b) (4) consecutive sets of swabbing 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 (e.g., zone 1) 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 zone 1 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) (b) (4) for stainless steel surfaces 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) sanitation procedure.

Following our (b) (4) sanitation 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) (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) and for *Lm* (b) (4), as under the routine program. We will collect (b) (4) finished product samples, which we will composite 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 zone 1 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 zone 1 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 3:

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

Specifically,

During the inspection, we observed condensate and drip throughout the facility. The following are examples of condensate that we observed dripping directly into ice cream products:

On 3/17/15, we observed condensate drip on line (b) (4) located on the 3rd floor in production area (b) (4) of the firm. The drip was falling from each of the (b) (4) blue hoses into the stainless steel mold. After the drip would fall on the molds, the molds containing the drip were filled with mix berry ice cream (lot 031717M).

On 3/18/15, we observed condensate above the filler on Pint line (b) (4) located on the 1st floor in production area (b) (4). The condensate was dripping directly into pints of mint chocolate ice cream (lot 031817D).

On 3/18/15, we observed condensate on the filler on 1/2 Gallon line (b) (4) located on the first floor in production area (b) (4). The condensate was dripping directly into 1/2 gallons of Cookies 'n Cream (lot 031817H).

On 4/21/15, we observed condensate drip on top of closed boxes of ice cream sandwich lids. The boxes containing ice cream sandwich lids were staged in the sandwich mezzanine room

on the second floor of the firm, under stainless steel ice cream lines which feed ice cream into sandwich production lines (b) (4). The lids are an ingredient used in the manufacture of ice cream sandwiches. Lines (b) (4) manufacture Vanilla Sandwiches, Mini Sandwiches (vanilla), and double vanilla sandwiches.

Response:

We are comprehensively reviewing our plant and equipment design and layout and have developed a multi-part response strategy to address the potential for contamination through condensation drip. We are evaluating our processing line layout and, when feasible, we are reconfiguring the layout so that pipes do not run above parts of equipment where condensation has the potential to come into contact with food or with food-contact surfaces. When reconfiguration is not feasible, we will insulate pipes to eliminate the temperature differences that cause condensation or we will install drainage troughs or splash guards to collect condensate and divert it away from the food-contact area. We are also evaluating replacing equipment, and we are planning a comprehensive engineering review to identify further ways to control condensation in the processing environment.

Under this plan, we are addressing the specific observations in the 483 as follows:

- Line (b) (4) Molds. We will install a condensate catch pan to collect any condensate drip and divert it away from the molds. The catch pan will be included in our routine cleaning and sanitation schedule.
- Pint Line (b) (4). We are working with our equipment supplier to redesign the filling equipment to eliminate the potential for condensate drip. We are also evaluating the potential to add a splash guard.
- Half Gallon Line (b) (4). We will replace the current (b) (4) filler with a (b) (4) filler that includes an integrated drip pan that will eliminate the potential for condensate to drip into the carton.
- Sandwich Mezzanine. We will insulate the overhead lines to prevent condensate formation.

Because we plan to resume production (b) (4), we will complete each of these actions before the relevant production line or area is brought online.

Observation 4:

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

Specifically,

On 3/16/15, we observed all (b) (4) of the ingredient hoppers in blending room (b) (4) were not kept clean. The underside of the hopper lids were caked with emulsifiers and stabilizers which had mixed with the humidity found in the room. These ingredients are added to blender (b) (4) along with other ingredients, such as cocoa powder, and blended with raw milk, prior to entering the High Temperature Short Time pasteurizer. Blender (b) (4) room is found on the first floor of the facility.

Response:

We have reviewed our ingredient hoppers—including those used in the Blender 1 Room—and replaced all ingredient hoppers with plastic containers that will be easier to maintain. The containers will feature (b) (4). The plastic containers will be (b) (4), and the plastic containers will be added to our master cleaning schedule. The regular cleaning and changing of the liners will prevent material build-up. We completed this change in April.

Observation 5:

Failure to wear beard covers in an effective manner.

Specifically,

On 3/16/15, we observed 6 employees with beards wear protective beardnets without covering the mustache portion of their beards. The employees were in various areas of the facility, including the HTST area, and in areas where the firm was actively producing products.

Response:

We have updated our good manufacturing practices (GMPs) to make clear that beard nets are required in processing areas for any facial hair that extends below the ears and that employees with mustaches are required to wear their beard nets directly under the nose, covering the mustache. We also prepared a graphic demonstrating the proper way to wear a beard net as well as the situations that would require a beard net be worn. We communicated this new policy to all employees on April 15, 2015, including the graphic, and we will include it in our future employee training before resuming production. We will maintain this policy for FDA onsite review.

Observation 6:

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

Specifically,

On 3/16/15, we observed paint on the ceiling vent directly above blender (b) (4) in the Blender (b) (4) and (b) (4) Room was chipped and cracking. Blender (b) (4) is used to add liquid ingredients and sugars into the raw milk product before it enters the High Temperature Short Time pasteurizers. We also observed that the door guards on the door at the entrance to the (b) (4) equipment room in production area (b) (4) had deep grooves, preventing the surface of the door guards to be easily cleaned.

Response:

The ceiling vent above Blender (b) (4) was cleaned, repaired, and repainted on March 29, 2015. In addition, as part of our whole-plant review, we are examining all surfaces for chipped, cracked, or peeling paint and will make any necessary repairs.

Blue Bell Creameries, Inc.
Brenham, Texas

Response to FDA Form 483
May 22, 2015

We will replace all the door guards, including the door guards on the door in the entrance to the (b) (4) room in Production Area (b) (4) with a material that will be easier to clean and that will not have the deep grooves identified in this Observation. We anticipate completing this work within (b) (4) days.

Index of Attachments to This Response

Attachment Name	Tab Number
FDA Form 483, Issued to Brenham Facility, May 1, 2015	1
Curriculum Vitae for (b) (4)	2
Curriculum Vitae for (b) (4)	3
Curriculum Vitae for (b) (4)	4
Curriculum Vitae for (b) (4)	5
Environmental Monitoring Program (Draft)	6
Routine Hold and Test Program (Draft)	7
Enhanced Hold and Test Program (Draft)	8

End of Detailed Response

Blue Bell Creameries
Detailed Response to FDA 483

Broken Arrow

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 Broken Arrow facility on April 23, 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 Broken Arrow facility from March 23, 2015, through April 23, 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 Broken Arrow, Oklahoma. As FDA is aware, on April 3, 2015, we voluntarily stopped all production at Broken Arrow, and we later stopped production at our other ice cream facilities as well. Since stopping production at Broken Arrow, we have been working tirelessly to identify and address issues that led to *Listeria monocytogenes* (*Lm*) contamination in some of our products. 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 of 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.

Earlier 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) 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) is (b) (4). (b) (4) He also serves as (b) (4). (b) (4) (b) (4) has authored numerous publications on food safety, and lectures and presents widely on the topic. (b) (4) 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) also brings more than three decades of food safety experience. He is (b) (4) for (b) (4). (b) (4) publishes and speaks widely on food safety and has extensive experience with developing food safety programs.
- (b) (4) also has nearly thirty years of food safety experience and is the (b) (4) (b) (4) for (b) (4). (b) (4) 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) has more than thirty years of experience with food safety and microbiology. (b) (4) is (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).

Early actions focused on identifying the root cause of the contamination. *Listeria* is a ubiquitous organism in the environment, and our challenge was to find and eradicate harborage sites in the plant and equipment. Initial efforts included systematically breaking down equipment and lines in a search for a primary harborage site. Preliminary evaluations indicate that cleaned equipment and sealed ingredient buckets not being used in production may have become contaminated with *Listeria* while being stored in a small room outside our sanitary production area. Our investigation indicated it was possible that atomized particles potentially carrying *Listeria* from time to time were released from a nearby drain in the room. If the equipment and the outside of these buckets were not cleaned successfully before being put back into the production area, they could have spread *Listeria* into product through employee and equipment contact. As explained more fully in response to Observation 7, we are no longer using this room for equipment storage. We have also identified the filler equipment as a potential source of introduction for *Listeria* into products. As explained more fully in response to Observation 5, we are taking corrective actions focused specifically on the fillers.

In addition to analyzing the root cause, we have worked tirelessly to clean and sanitize our facility, a process facilitated by our decision to completely stop production. We are systematically cleaning and sanitizing all parts of 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.

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 manufacture and package foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, you manufactured ready-to-eat, frozen, dairy desserts which tested positive for *Listeria monocytogenes*. The following finished product manufactured by your firm tested positive for *Listeria monocytogenes*.

- A. Institutional Chocolate Ice Cream in a 3oz cup with a pull tab lid, Lot code 041516Q, produced on 04/15/2014, tested positive for *Listeria monocytogenes* by the Kansas Department of Health and Environment. Your firm distributed all (b) (4) 3oz cups of this lot between 04/15/2014 and 03/23/2015.
- B. (b) (4), produced on 03/23/2015, tested positive for *Listeria monocytogenes* by a third party laboratory selected by your firm. You reported you did not distribute any of the (b) (4), to your customers.
- C. Banana Pudding Ice Cream, Lot code 021217S, produced on 02/12/2015, tested positive for *Listeria monocytogenes* by the FDA. Your firm distributed (b) (4) pints of the Banana Pudding Ice Cream, Lot code 021217S, to your customers between 02/12/2015 and 03/26/2015.

Subsequently, your firm initiated a voluntarily recall of all institutional ice cream products in a 3oz cup with a pull tab lid on 03/23/2015. On 04/07/2015, your firm expanded the voluntary recall to include all products manufactured on Slot (b) (4) after 02/12/2015. Then on 04/20/2015, your firm expanded the voluntary recall to include all products manufactured by your firm.

Response:

Since the initial recall, we have strived to act responsibly based on the best evidence available at the time, always with the objective of protecting our consumers. We have also worked hard to maintain clear, open communications with FDA, our state regulators, and our customers, recognizing that public health is best protected if we all work together.

We were informed on March 22, 2015, that an institutional ice cream product in a 3 oz cup produced at our Broken Arrow facility and sampled by Kansas officials had tested positive for *Lm*. The next day, we recalled three flavors of our 3 oz ice cream cups sold for institutional and food service use—chocolate (SKU #453), strawberry (SKU #452) and vanilla (SKU #451). After continued analysis—including our own tests that returned an *Lm* positive result in (b) (4)

product, 1/ which was never distributed—we elected on April 3, 2015, to voluntarily suspend operations at Broken Arrow and to recall all products produced by the Broken Arrow facility. The Banana Pudding Ice Cream referenced in the Observation was included in that recall.

Observation 2:

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

Specifically,

- A. You stated the results of your sampling for environmental pathogens on non-food contact surfaces as defined in your 04/22/2014 written procedure entitled "Plant Environmental Testing" were used as an indicator in determining whether the cleaning and sanitizing program was effective. However, this sampling program failed to include the following:**
- a. Sampling of food contact surfaces.**
 - b. Determination of any preventative 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.**
 - e. Root Cause Analysis of why the cleaning and sanitizing treatments were inadequate in controlling the occurrences of microbiological contaminations.**
- B. You also stated the results of your daily total coliform sampling on finished product, in-process product, and raw ingredients added post pasteurization were used as an indicator in determining whether the cleaning and sanitizing program was effective. However, this sampling program failed to include the following:**
- a. Determination of any corrective or preventative action needed in response to the possible contamination.**
 - b. Determination of the impact on the products produced on the affected date.**
 - c. Determination of the pathogenicity of the coliform isolates.**
 - d. Root Cause Analysis of why the cleaning and sanitizing were inadequate in controlling the occurrences of microbiological contaminations.**

^{1/} According to our records, the (b) (4) product referenced in sub-observation B was produced on March 20, 2015, not March 23, 2015, as noted in the 483. Accordingly, the correct lot code is (b) (4).

e. Establishment of alert and action limits.

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 zoned 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)} environmental swabs from zones 2–4 (non-food contact surfaces) (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, (b) (4), using (b) (4) (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 zone 1 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 re-swab the site and will take (b) (4) additional vector swabs from points within a (b) (4) radius 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 vector swabbing until (b) (4) consecutive sets of swabbing 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 (e.g., zone 1) 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 zone 1 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 (b) (4), which we will test for (b) (4) readings. We will apply a threshold of (b) (4) (b) (4) for stainless steel surfaces 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) sanitation procedure.

Following our (b) (4) sanitation procedure, we will collect (b) (4) samples from randomly chosen locations on food contact surfaces on (b) (4), 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) (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) and for *Lm* (b) (4), as under the routine program. We will collect (b) (4) finished product samples, which we will composite 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 (b) (4). 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 zone 1 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 zone 1 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.

Observation 3:

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

Specifically, you failed to demonstrate your cleaning and sanitizing program is effective in controlling recurring microbiological contaminations. You continued to have presumptive positive environmental test results for *Listeria spp.* and elevated total coliform results following the daily cleaning and sanitizing treatments of your equipment and facilities. You reported the results of the sampling program were used as an indicator in determining whether the cleaning and sanitation program was effective. In response to presumptive positive environmental test results for *Listeria spp.* and the elevated total coliform counts, you reported the usual cleaning and sanitation procedures were followed and verified as being performed more thoroughly during the next cleaning and sanitizing cycle after notification of the results; which may be (b) (4) days for *Listeria spp.* and (b) (4) for in-house total coliform. Examples of microbiological contamination of production equipment and finished product are as follows.

- A. *Listeria spp.* was isolated from non-food contact areas within the processing room and kitchen and from non-food contact surfaces of production equipment. These included 5 samples in 2013, 10 samples in 2014, 1 sample in January, and 1 sample in February of 2015. In addition, environmental samples collected by the FDA on 03/24/2015 and 03/25/2015 tested positive for *Listeria monocytogenes*.

[Table omitted]

On 01/13/2014, the (b) (4) was sampled, and the sample was sent to your 3rd party laboratory who received the samples on 01/14/2014. The laboratory reported the sample from the (b) (4) as presumptive positive for *Listeria spp.* on 01/16/2014. The (b) (4) was re-sampled on 01/20/2014 and the samples were reported by the laboratory as presumptive positive for a second time on 01/23/2014. The (b) (4) was documented as being cleaned and sanitized after (b) (4) between 01/13/2014 and 01/17/2014, however, it failed to be cleaned and sanitized adequately and showed evidence of *Listeria spp.* on two consecutive samples.

On 04/15/2014, (b) (4) at ½ Gallon Filler was sampled, and the sample was sent to your 3rd party laboratory who received the samples on 04/16/2014. The

laboratory reported the sample from the (b) (4) at ½ Gallon Filler as presumptive positive for *Listeria spp.* on 04/19/2014. The (b) (4) at ½ Gallon Filler was re-sampled on 04/22/2014 and the samples were reported by the laboratory as presumptive positive for a second time on 04/25/2014. The (b) (4) at ½ Gallon Filler was documented as being cleaned and sanitized after the daily production between 04/15/2015 and 04/21/2014, however, it failed to be cleaned and sanitized adequately and showed evidence of *Listeria spp.* on two consecutive samples.

- B. Total coliform greater than 20 Colony Forming Units (CFUs)/mL was identified in finished, in-process product batches, and raw ingredients in 6 samples during April 2014, 8 samples during January 2015, 23 samples during February 2015, and 10 samples during March 2015. You reported the Oklahoma Department of Agriculture, Food, and Forestry had a regulatory requirement of 20 CFUs/mL, or less in finished products of frozen dairy desserts.

[List identifying samples that exceeded 20 CFU/mL omitted]

Response:

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 thoroughly clean all processing equipment to remove organic buildup and other residue, disassembling any equipment as necessary. We plan to (b) (4) that helps complete and (b) (4) and then focuses entirely on cleaning the processing area. After cleaning, we will sample randomly selected food contact surfaces on equipment and test them for (b) (4) to verify cleaning, as described in response to Observation 2. 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. After (b) (4) sanitation, we will sample randomly selected food contact surfaces for *Lm* to verify sanitation, again as described in response to Observation 2. Any presumptive positives for *Lm* will trigger immediate corrective action as well as the destruction of the previous days' production from that line.

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 4:

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

Specifically, you reported the water temperature for the washing and rinsing of the exterior surfaces of the equipment and COP was not continuously monitored, verified,

or documented. You also reported the water temperature for the CIP system used to clean and sanitize the food contact surfaces of the mix tanks, flavor tanks, freezers, fillers, and connecting pipes was not continuously monitored, verified, or documented. However, you stated the water heater was set to heat the water to a temperature between (b) (4)°F and (b) (4)°F.

The labeling on the (b) (4) sanitizer, which you use in CIP and COP procedures, states in part, "****To CIP product lines, use (b) (4) ounces of (b) (4) per one gallon of (b) (4) (b) (4)°F water for (b) (4) (b) (4) minutes (minimum of (b) (4) minutes at temperature (b) (4) (b) (4)°F. To CIP cold product storage tanks, use (b) (4) ounces per one gallon of (b) (4) (b) (4) °F water**** (b) (4) should be used at a concentration of up to (b) (4) in water at (b) (4)°F for (b) (4) minutes in a soak tank, or less time if (b) (4) .****".

On 03/30/2015, you were asked to perform a check on the start-up and final water temperatures during the usual cleaning and sanitizing procedures. Following (b) (4) (b) (4), you reported the CIP temperature ranged from 122°F at start-up to 118°F at final. You also reported the COP water temperature was 128°F. These temperatures failed to meet the usage instructions on the (b) (4) label.

Response:

We have evaluated our water-temperature control processes and have determined that adding additional heating capacity will improve our ability to maintain targeted water temperatures. Specifically, we will add an (b) (4) water heater dedicated to our clean in place (CIP) and clean out of place (COP) systems. We have contracted with an engineering company specializing in water heating solutions to (b) (4) with our CIP and COP water systems. The (b) (4), ensuring a (b) (4) (b) (4) at the target temperature. The heater will provide adequate hot water needed for our CIP and COP systems. The new heater will allow us to reliably maintain the temperatures recommended for the detergent and other cleaning and sanitizing functions. The heater is scheduled to be installed within (b) (4) days.

In addition to adding a specialized heating unit dedicated to our CIP and COP systems, we will install a (b) (4) to control our CIP and COP operations. The (b) (4) will continuously monitor water temperature and will stop the cleaning cycle and alert the sanitation operator if the water temperature drops below the programmed threshold; the system will resume cleaning once the appropriate water temperature is achieved. The (b) (4) will also be programmed to run the cleaning cycle at validated time and water temperature parameters. Each employee will be assigned a unique code that must be entered to start the (b) (4) system, and the (b) (4) will output time and temperature data to our computer systems. As a result, we will be able to identify for each CIP and COP cycle the water temperature, the cleaning time, and the employee performing the task. We anticipate installing the (b) (4) system within (b) (4) days.

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.

Specifically, on 03/26/2015 condensation was observed in the following areas:

- A. A continual line of condensate droplets were observed along the bottom of stainless steel Product Supply Lines (b) (4) and (b) (4). These approximately (b) (4) inch diameter product lines are installed horizontally above all (b) (4) Flavor Tanks and supply the product mixes from the basement mixing tanks. The condensate was observed dripping down onto the tops of the enclosed Flavor Tanks, however, the (b) (4) of the (b) (4) (b) (4) enter the tanks through a hole in the top of each tank and the gaskets between the tanks and the (b) (4) are not tight fitting and do not prevent the entry of the condensate. Additionally, the Mix Tank Operators at Flavor Tank #s (b) (4) and (b) (4) which contained Dutch Chocolate Supreme Ice Cream, Batch 130321, Lot code 032617Q, Slot # (b) (4) and Flavor Tank # (b) (4) which contained Caramel Sundae Crunch Ice Cream, Batch 131906, Lot code 032617S, Slot # (b) (4) were observed spraying the tops of the tanks with a water hose which washed the condensate into and around the gaskets and (b) (4) potentially contaminating the ice cream mixes in the Flavor Tanks. The ice cream mixes were post-pasteurization and "in line" to the (b) (4) freezers and packaging. The Mix Tank Operators were also observed hanging an ingredient mixing pitcher from one of the Product Supply Lines and storing other pitchers on the tops of the Flavor Tanks; potentially contaminating the pitchers with condensate.
- B. At Flavor Tank #s (b) (4) and (b) (4) the Mix Draw Operator was observed removing the round tank lids and placing them directly on the top of the Flavor Tanks with the underside of the lids directly contacting condensate droplets which were dripping from Product Supply Line #s (b) (4) and (b) (4). The Flavor Tanks were being used to mix Dutch Chocolate Supreme Ice Cream, Batch 130321, Lot code 032617Q, Slot # (b) (4). After ingredients were added to the Flavor Tanks, the Mix Draw Operator placed the lids back over the openings of the tanks potentially contaminating the post-pasteurized ice cream mix with condensate from the lids.
- C. Condensate was observed dripping from the Slot # (b) (4) Filler Head into quart containers of Orange Sherbet, Batch 131444, Lot code 032617S, while the product was being filled and packaged between (b) (4) and (b) (4). The production of the Orange Sherbet started at (b) (4) and ended at (b) (4); producing (b) (4) quarts.
- D. Condensate was observed dripping from Product Supply Lines (b) (4) and (b) (4) onto the top of cardboard cases of (b) (4), 1/2 Gallon, Caramel Sundae Crunch Ice Cream containers which were stored directly below the lines and adjacent to Flavor Tank # (b) (4). The cases of containers were staged below the dripping product supply lines until needed at Slot # (b) (4) which was filling and packaging Caramel Sundae Crunch Ice Cream, Batch 131906, Lot code 032617S.

Response:

We have comprehensively reviewed our plant and equipment design and layout and have identified changes in light of the recent experiences. Part of that review focused on control of condensation

and the potential for dripping caused by overhead pipes. As part of that holistic review, we have taken the following steps in response to each lettered portion of this observation:

A. Overhead Supply Lines Over Flavor Tanks

As part of our internal review, we are extensively reconfiguring lines and equipment to eliminate the potential for condensation forming on pipes above processing equipment. Whenever feasible, we are moving equipment or lines so that lines no longer run directly above equipment. The supply lines above the flavor tanks represent a situation in which it simply is not feasible to reconfigure the equipment layout. Instead, we are installing troughs under the overhead supply lines to catch any condensation that may drop from the supply lines and channel it away from the flavor tanks (and other equipment under the lines). The troughs will be included in our regular cleaning and sanitation schedule.

The gaskets on the top of the flavor tanks around the (b) (4) are designed to prevent contamination from water and other substances dropping or splashing into the flavor tanks from above or the side. We are evaluating the gaskets to ensure they fit tightly and are replacing them as needed. We will also lower the temperature of the processing room to decrease the temperature differential between the pipes and the ambient air, reducing condensation formation. Moreover, we will conduct employee training on the proper handling of equipment, including not placing pitchers and other containers on top of the flavor tanks. Finally, we will evaluate how to revise our cleaning procedures to minimize the likelihood that cleaning the top of the flavor tanks could contaminate product.

B. Tank Lids on Flavor Tanks

The Mix Draw Operator was not following proper procedures when placing the flavor tank lid underside-down on top of the flavor tank. As mentioned above, employees will be retrained on how to handle items such as containers and pieces of equipment that may come into contact with food, including the proper handling of machine lids.

Flavor Tanks (b) (4) and (b) (4) are the only flavor tanks that have fully removable lids. All the rest of our flavor tanks have lids that are attached to the equipment with hinges. When the lids are opened, the hinges hold them in place so that only the outside of the lid touches the outside of the flavor tank (if any part of the lid touches the flavor tank at all), making it impossible for this Observation to occur for the other flavor tanks. We are modifying Flavor Tanks (b) (4) and (b) (4) so that their lids are also attached by hinges, ensuring the observed handling of the lids cannot occur. We completed this change this month.

C. Condensation Dripping into Quart Containers

As part of our reconfiguration of the plant, we (b) (4) at Broken Arrow for the foreseeable future, and we are (b) (4). We have, however, reviewed all of our filling machines in light of this observation and are developing a series of engineering solutions to address the potential for contamination. We will (b) (4) machine to eliminate to the extent possible piping, clamps, valves, and other parts that could create contamination above the containers. We are also evaluating the feasibility of using non-metal components for certain parts of the equipment. Further, we are evaluating the feasibility of using

splash shields that will catch any condensation over open quart containers and direct it away from the containers being filled.

We are also, as part of our overall review of our production line layout, reconfiguring the lines leading into the filling machines to minimize the extent to which lines run over parts of the filling equipment. Lowering the production room temperature should also help reduce condensation formation.

We anticipate completing the evaluation within (b) (4) days.

D. Condensate Dripping onto Cardboard Cases of Containers

We have reevaluated our equipment configuration and are making changes to our equipment layout to eliminate the potential for condensate to drip onto containers waiting to be filled. Our packaging line consists of (b) (4) primary pieces of equipment. Ice cream containers (consisting of lids and cups) are loaded into (b) (4) of (b) (4) pieces of equipment—(b) (4)—which feed the containers (b) (4) into the filling equipment to be filled and capped. Cardboard cases of ice cream containers are stored near the (b) (4) and (b) (4), and an employee is responsible for (b) (4). We have moved the necessary equipment so that the cardboard boxes of ice cream containers can be stacked next to the equipment without being under any overhead pipes. We have already moved the equipment, and we anticipate finishing the reconfiguration of overhead pipes within (b) (4) days.

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.

Specifically, the following instances of failure to change gloves and wash hands were observed on 03/26/2015:

- A. At Flavor Tank # (b) (4) the Mix Draw Operator was observed touching non-food contact and food contact surfaces with the same pair of gloved hands. The Mix Draw Operator was also observed checking the volume in Flavor Tank # (b) (4) which contained Caramel Sundae Crunch Ice Cream, Batch 131906, Lot code 032617S, Slot # (b) (4) by directly wiping product off the metal dipstick with his gloved hand, while the product drained back into the tank, and then he returned the dipstick back into the Flavor Tank. The Mix Draw Operator did not perform a hand wash or glove change prior to touching the product on the dipstick.
- B. At Flavor Tank # (b) (4) the Mix Draw Operator and Freight Puller were observed lifting and pouring orange puree from plastic buckets into the Flavor Tank which contained Orange Sherbet, Batch 131444, Lot code 032617S, Slot # (b) (4). The Mix Draw Operator and Freight Puller used gloved hands to pick up the buckets by the sides and bottoms while transferring from one to the other. The buckets on the bottom row were stored directly on the wet, wood pallets which had black mold-like residue and red stains.

The Freight Puller was observed alternating hands while picking up the buckets by the bottom and occasionally his fingers would contact the top rim and the inside of the puree buckets; possibly contaminating the food contact surface with the gloved fingers which directly touched the bottom of the buckets.

- C. At the (b) (4) Freezer #^{(b) (4)} the Machine Operator was observed rubbing the product line of Freezer #^{(b) (4)} scraping (b) (4) product off the (b) (4) of the filler, turning the product line valve to divert product to a (b) (4), adding chocolate chips into the fruit feeder, making adjustments to the filler equipment, and adjusting his hairnet and hat. All of the tasks, including directly touching product to be (b) (4), were performed with the same pair of gloves while pints of Chocolate Chip Cookie Dough Ice Cream, Batch 132149, Lot code 0326170, Slot #^{(b) (4)} were being packaged.

This is a repeat violation from the 2012 FDA inspection.

Response:

We are comprehensively reviewing our employee hygiene good manufacturing practices (GMPs) as well as how we communicate with employees about proper sanitary interaction with equipment and food. We are also reviewing our processes to identify and eliminate opportunities for mistakes.

We are revising our GMPs to reinforce that employees are to thoroughly wash and sanitize their hands, change single-use gloves, or sanitize multi-use gloves—as appropriate—between touching a non-sanitized surface and product or a food contact surface. For example, we are emphasizing with employees that if they are picking up a series of containers to pour ingredients into a mixer, they must hold each container in the same way, with the same hand touching the part of the container that may come into contact with product each time and without touching anything with that hand that has not been sanitized. Enhanced employee training will also focus on identifying the differences between food-contact surfaces and non-food-contact surfaces. Training will also focus on the importance of wearing proper protective attire, such as smocks, hairnets, and beardnets, as well as the importance of ensuring that employees' clothing does not touch food-contact surfaces when employees are interacting with equipment. All employees will undergo extensive retraining prior to startup, including with respect to employee hygiene and GMPs.

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 re-introduction of *Listeria* into our facility.

Finally, we will install (b) (4) at all entrances into wet processing areas. The (b) (4) will (b) (4). The (b) (4) for each doorway to ensure a constant coverage. The (b) (4) will ensure that the wheels or shoes of anything or anyone entering the sanitary area—whether an employee, a forklift, or a handcart—will be sanitized before entering the production area. (b) (4) installation is underway, and we anticipate completing installation within ^{(b) (4)} days.

Observation 7:

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

Specifically, on 03/23/2015, food contact equipment used in processing and packaging including (b) (4) 3oz cup fillers, packaging chutes, conveyors, and tables were observed in the basement. The area where the equipment was being stored was hot and humid due to the adjacent (b) (4) . All of the equipment was observed uncovered and unprotected with condensate dripping directly onto random sections and surfaces. You reported the equipment was cleaned and sanitized after its last production run and then relocated into the basement area. You also reported the area was classified as non-sanitary and after the pieces of equipment are moved back to the production slot and installed, the equipment is sanitized prior to usage.

Response:

The equipment being stored was not in use, and the storage area was not intended to be a sanitary space. As the Observation notes, equipment stored in this location would be cleaned and sanitized before being placed back into production. In light of the investigator's observations during the inspection, we have discontinued the practice of storing out-of-service equipment in this location, and we moved equipment out of this area in April. We are evaluating our overall facility design to identify an appropriate permanent storage location for equipment not currently being used. In the interim, we will store unused equipment in a sanitary space that is routinely sanitized and included in our environmental monitoring program. Going forward, equipment taken off the line will be cleaned and sanitized before being moved to the storage space, and it will also be cleaned, sanitized, and evaluated before being put back into production. We are setting up a permanent location for this cleaning and sanitization process. Further, we have used this process as an opportunity to evaluate and substantially reduce the number of excess pieces of equipment that will be kept on-hand in the facility, which will make storage easier.

Observation 8:

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

Specifically, you do not have cleaning and sanitizing procedures for employee shoes worn into the sanitary food production areas of the firm to ensure that any possible contamination risks are minimized. Shoes are worn out of the firm to employee's vehicles and homes and then back into the sanitary food production areas each day without any cleaning and sanitizing requirements. In addition, employees were observed traveling from sanitary food production areas to non-sanitary areas including dry goods storage, maintenance shop, offices, break room, outside smoking areas, and milk truck delivery bays without cleaning and sanitizing prior to re-entry into the sanitary food production areas between 03/23/2015

and 03/27/2015. The only (b) (4) are located at the swinging doors of the Kitchen leading into the processing area and into the garbage collection area and in the HTST area leading into the garbage collection area. The (b) (4) are on (b) (4) spray intervals and do not cover the entire distance of the entryways.

Response:

As noted in response to Observation 6, we are implementing clothing policy that will ensure employees are wearing clean coverings, including clean footwear or coverings, while in the sanitary processing area. Employees will not be permitted to wear unprotected street shoes into the processing areas. As also noted in response to Observation 6, we are installing (b) (4) at all entrances to wet processing areas. The (b) (4) to cover the entire distance of each doorway, and they will (b) (4) as needed for the particular doorway.

Observation 9:

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

Specifically, wood pallets which are porous and not easily cleanable are used throughout your firm to store and transport raw ingredients, finished product, and packaging materials. The wood pallets were observed in different stages of damage and disrepair while they were being used in the kitchen, warehouse, freezer, production, and mixing areas. The top platform, bottom, and corners of the pallets were broken, discolored, and soiled. The wood pallets were also observed to be saturated from being used in the wet processing areas and were observed as having black mold-like residues and red stains. The following are examples of the pallet usage observed on 03/26/2015:

- A. Plastic buckets containing Orange puree were stored on wood pallets by Flavor Tank (b) (4). The Orange puree was hand added as an ingredient to the pasteurized Orange Sherbet mix in Flavor Tank # (b) (4) on Slot # (b) (4). The finished product was Orange Sherbet, Batch 131444, Lot code 032617S.
- B. Plastic buckets containing thawed (b) (4) Sliced Strawberries, Lot (b) (4) were stored on wood pallets in the Kitchen awaiting the addition of granulated sugar in the (b) (4).
- C. Reusable cardboard sleeves used for palletizing finished product and cardboard cases of 1/2 Gallon ice cream containers were stored on wood pallets located in the production area.

Response:

We are discontinuing the use of wood pallets in the production and processing areas, including the kitchen (the sanitary areas of our facility). We are evaluating various options, which may include using plastic pallets that can be cleaned and sanitized on a regular basis.

For incoming shipments that will be stored outside the sanitary areas of the facility, we will work with our suppliers to transition to alternatives to wood pallets when feasible. When incoming ingredients are supplied on wood pallets, we will ensure that the pallets do not become a potential source of contamination in the sanitary processing areas.

Observation 10:

Failure to hold foods which can support the rapid growth of undesirable microorganisms at a temperature that prevents the food from becoming adulterated.

Specifically, between 04/11/2014 and 04/13/2014 there were several elevated temperature excursions above 45°F in unpasteurized milk products which are used as raw ingredients. These included the chocolate (b) (4) stored in Raw Tank (b) (4) which was used in the Institutional Chocolate Ice Cream, Lot code 041516Q, produced on 04/15/2014. The excursions above 45°F were documented on the (b) (4) Lab Report and the (b) (4) Temperature Recorders. Examples include the following:

- A. On 04/12/2014, Raw Tank # (b) (4) contained chocolate (b) (4). The AM and PM temperatures were documented as being 47°F
- B. On 04/12/2014, Raw Tank # (b) (4) contained (b) (4) cream. The AM and PM temperatures were documented as being 46°F
- C. On 04/13/2014, Raw Tank # (b) (4) contained skim milk. The AM temperature was documented as being 48°F and the PM temperature was documented as being 46°F
- D. On 04/13/2014, Raw Tank # (b) (4) contained cream rinse. The AM and PM temperature were documented as being 50°F

Response:

The products identified in the Observation were being held in our raw area and were all subjected to a pasteurization process before being used to produce ice cream. We believe the minor temperature variations identified in this Observation did not present a risk of significant pathogen outgrowth capable of overwhelming the pasteurization process. Nevertheless, we aim to avoid unnecessary temperature variations, and we will ensure that the temperatures of the raw tanks are monitored on an ongoing basis.

Moreover, several of these temperature fluctuations were aberrations. The temperature variations identified in sub-observations A through C resulted from an accident that damaged our plant's electrical system. An individual ran his car off the road, through our fence, and onto our property, damaging part of our power equipment. Power was maintained in our facility following the accident, but repairs were necessary. Once we obtained replacement equipment, we had a planned power outage to repair the damage. To prepare ingredients, we pasteurized the materials identified in sub-observations A through C, transferred them back into our raw storage tanks, powered down to complete repairs, and then re-pasteurized the ingredients once power was restored. We believe this process was appropriately protective of product safety.

Sub-observation D reflects procedures necessary to remove cream from a tanker. Cream develops a substantial head of foam when held in a tanker, representing a significant portion of the overall volume of the cream. Fully extracting the foam requires (b) (4) of hot water to reduce the foam; cold water does not have the necessary effect (after rinsing, the amount of water can be determined and the ingredient composition adjusted accordingly). We understand this procedure reflects standard industry practice. Typically, we (b) (4)

(b) (4)

(b) (4)

(b) (4)

. We believe this practice is consistent with proper handling of cream. For example, USDA's Agricultural Marketing Service (AMS) standards for milk and cream state that raw milk shall be held at 45 °F or lower until processing begins but allows that "[t]his does not preclude holding milk at higher temperatures for a period of time, where applicable to particular manufacturing or processing practices." 7 C.F.R. 58.143(a). In all cases, the rinsed cream is cooled to 45 °F and is pasteurized before being used to produce ice cream.

Observation 11:

Failure to have smoothly bonded or well maintained seams on food contact surfaces, to minimize accumulation of food particles and organic matter and the opportunity for growth of microorganisms.

Specifically, the stainless steel (b) (4) mixer, referred to as the (b) (4); had rough welds and non-continuous welds along the back and side splash guards located on top of the tank. The welds, approximately (b) (4) linear feet in length, are hard to clean and create areas where food particles and microorganisms could harbor. On 03/26/2015 the (b) (4) was observed being used in the Kitchen to mix granulated sugar and thawed (b) (4) Sliced Strawberries, Lot code (b) (4) for the eventual addition to batches of pasteurized ice cream mixes.

Response:

Much of our equipment must be customized to reflect our specific manufacturing processes, sometimes requiring modifications by our (b) (4). In the case of the (b) (4), the splash guards were added to prevent the ingredients from splashing out of the machine. We reviewed this piece of equipment, decided the splash guards are no longer needed, and removed them. FDA's Observation and the voluntary stopping of production presented an opportunity to reevaluate our processing equipment. We are reviewing the equipment used in the sanitary areas to ensure welds do not present potential harborage sites. This effort has resulted in us reviewing thousands of welds, including significant rewelding and smoothing. This process has (b) (4)

This process has also facilitated our systematic inspection, cleaning, and sanitization of every piece of equipment in our production area. Before being reintroduced into the sanitary area, equipment will be fully cleaned, sanitized, and evaluated.

Observation 12:

Failure to take apart equipment as necessary to ensure thorough cleaning.

Specifically, the front face plate of the (b) (4) Freezer #^{(b)(4)} is not disassembled to thoroughly clean the white gasket which ensures there is no leakage of the ready-to-eat ice cream and sherbet. On 03/22/2015, the faceplate was removed for environmental sampling and the gasket was observed to have black mold-like residual on the flat portions of the gasket which forms the seal against the faceplate and the freezer body. Freezer #^{(b)(4)} was last used in the 03/20/2015 production of the Institutional Vanilla Ice Cream in a 3oz cup with a pull tab lid, Batch 130043, Lot code 032017Q. Freezer #^{(b)(4)} was reported to be "clean" following the CIP, wash, and sanitization performed on 03/20/2015.

Response:

We are adding the front face plate of each (b) (4) freezer and their corresponding gaskets to our master cleaning schedule. These components will also be included in our routine sampling program. We will continue to monitor the gaskets and will take additional corrective action if needed to prevent them from becoming a potential source of contamination.

Index of Attachments to This Response

Attachment Name	Tab Number
FDA Form 483, Issued to Broken Arrow Facility, April 23, 2015	1
Curriculum Vitae for (b) (4)	2
Curriculum Vitae for (b) (4)	3
Curriculum Vitae for (b) (4)	4
Curriculum Vitae for (b) (4)	5
Environmental Monitoring Program (Draft)	6
Routine Hold and Test Program (Draft)	7
Enhanced Hold and Test Program (Draft)	8

End of Detailed Response