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July 21, 2015

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

Re: 60-Day Update on Response 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 provide this 60-day update on the status of the corrective actions we identified in our responses 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 status of our corrective actions in response to the FDA Form 483 issued to our facility in Sylacauga, Alabama.

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

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

have continued work in our facilities in Brenham, Texas, and Broken Arrow, Oklahoma. We continue to move forward with key infrastructure and equipment modifications in each of these facilities, and we plan to incorporate learnings from the planned (b) (4) at our Sylacauga facility when updating our procedures for Brenham and Broken Arrow.

As we begin to focus on (b) (4) at our Sylacauga facility and completing corrective actions in our Brenham and Broken Arrow facilities, we want to assure FDA that we remain committed to cooperating fully and communicating openly with FDA and our state regulators. We want to be sure that FDA is fully comfortable with the steps we are taking at all of our facilities. Importantly, as we move to resume (b) (4) at our Sylacauga facility (and, ultimately at some point in the future, our Brenham and Broken Arrow facilities), we will operate under our (b) (4) program, and we will not release any product from inventory until we, FDA, and the states are comfortable the product is safe for our consumers to enjoy.

As with our earlier responses, we are copying Ruth Dixon, Director of the New Orleans District Office to this cover letter, and we will copy you on our companion update on our efforts in 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
Blue Bell Creameries, Inc.

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

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

Gary Jay Kushner
Counsel to Blue Bell Creameries, Inc.

Enclosures

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

Tab II: Blue Bell Creameries, Inc., Update to FDA Regarding Corrective Actions in Response to 483 Issued to Broken Arrow, Oklahoma, Facility

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

July 21, 2015

Blue Bell Creameries (Blue Bell or the Company) appreciates the opportunity to provide this update to the Food and Drug Administration (FDA) regarding corrective actions taken at our ice cream manufacturing facility in Brenham, Texas, in response to the FDA Form 483 Inspectional Observations (the 483) issued to our facility on May 1, 2015.[1] In our May 22, 2015, response to the 483, we outlined a number of corrective actions in response to FDA's observations and committed to providing an update on our corrective actions in 60 days. We thank FDA for allowing us the opportunity to provide this 60-day update.

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

This update identifies the current status of the corrective actions identified in our initial 483 response but not yet completed when that response was submitted. As we have explained to FDA, we have focused efforts on resuming production first at our facility in Sylacauga, Alabama. We therefore have devoted substantial attention to completing modifications to the equipment, infrastructure, and procedures for that facility. We plan to use what we learn in the process of bringing that facility back into operation to inform our approach to continued corrective actions in our Brenham facility.

Although we have focused significant attention and resources on our facility in Sylacauga, we have not been idle in Brenham. We have been hard at work cleaning and sanitizing equipment and the facility, including (b) (4) to allow for (b) (4). We have also been making numerous facility and infrastructure improvements not directly related to any Observation in the 483 but intended to enhance our ability to produce safe, wholesome ice cream at Brenham. Because of these decisions, many of the detailed corrective actions identified in our 483 response remain to be completed. This is simply a matter of sequencing and prioritization. (b) (4) (b) (4), for example, so we have not had an opportunity to complete the modifications we intend to make when (b) (4). We identify in this update to

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

the extent possible anticipated completion dates for these equipment modifications, but a number of variables—including our experiences with our other facilities—could cause these anticipated dates to shift.

Likewise, we have prioritized developing procedures and programs to support operations at our Sylacauga facility. Some of these procedures reflect company-wide programs. We identify such programs in this update. Other procedures are specific to operations at our Sylacauga facility but will translate to Brenham operations with some amount of modifications. Because we do not intend to (b) (4), we intend to wait to modify or finalize these latter procedures for our Brenham facility until we gain more experience with them during (b) (4) at our Sylacauga facility. We fully intend to incorporate any learnings from these programs at our Sylacauga facility into the procedures we finalize for our Brenham facility.

Moreover, although we do not plan to (b) (4), when we do resume operations, our tentative plan is to begin (b) (4). To that end, we are prioritizing completing corrective actions that will affect the equipment and procedures required to (b) (4), with the intent to continue implementing corrective actions and modifications on (b) (4) before it is (b) (4).

We appreciate FDA's understanding of this complicated corrective action sequence and the (b) (4) to implementing corrective actions that results from it. We remain committed to providing FDA with updates on our progress at our Brenham facility, and we plan to provide another update 60 days from today (120 days from our original 483 response) informing FDA of the status of the remaining corrective actions.

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

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

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

We committed to providing revised cleaning and sanitation procedures to FDA once the procedures are complete. We have focused our efforts company-wide on reviewing the cleaning and sanitation procedures that pertain to the equipment and processing lines we hope to bring back into operation first in our Sylacauga facility. Accordingly, we have not yet completed the review of cleaning and sanitation procedures (b) (4), although we fully intend to do so (b) (4). As was our approach with our Sylacauga facility, we will first

focus our attention on those cleaning and sanitation procedures necessary to support the (b) (4) (b) (4), and we will expand our review to include additional procedures as they become necessary to support (b) (4). We anticipate using common cleaning and sanitation procedures across our facilities to the extent possible, and we will apply any learnings from our initial startup operations at our Sylacauga facility to our review of cleaning and sanitation procedures for our Brenham facility. At this point, we cannot (b) (4) (b) (4), but we remain committed to keeping FDA informed of our efforts to review and modify as appropriate our cleaning and sanitation procedures for our Brenham facility.

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

We identified a number of steps in response to this Observation, all of which remain a work in progress because (b) (4). We have identified the following anticipated completion dates for these items as they relate to the equipment that we anticipate would be used during (b) (4):

- Reconfigure pipe and line layout to minimize potential for condensation to come into contact with food or food contact surfaces. We anticipate completing this work by (b) (4) for areas and lines that would be used during (b) (4). We would continue addressing other areas and lines as (b) (4).
- Insulate pipes or install splash guards when reconfiguration is not feasible. We anticipate completing this work by (b) (4), for areas and lines that would be used (b) (4) (b) (4). We would continue addressing other areas and lines as they are (b) (4).
- Add (b) (4) to Line (b) (4) Molds. We anticipate completing this work by (b) (4) (b) (4)
- Add (b) (4) on Line (b) (4) Molds to master sanitation schedule. We anticipate adding the (b) (4) to the master sanitation schedule once they are installed. The Master Sanitation Schedule remains a work in progress as we make modifications to our facility and equipment. We anticipate completing it by (b) (4).
- Modify (b) (4) Line (b) (4) filling equipment to address potential for condensation drip. We anticipate completing this work by (b) (4).
- Replace (b) (4) on (b) (4) Line (b) (4) We anticipate completing this work by (b) (4).
- Insulate overhead lines in sandwich mezzanine. After further consideration, the (b) (4) (b) (4). We do not know (b) (4) or whether we would (b) (4). We are therefore are holding this corrective action in abeyance pending further evaluation of this space. Should we (b) (4) in this space, we will insulate the pipes or take other steps to control condensation. At this time, we cannot predict an anticipated completion date.
- Engineering review for condensation control. We anticipate completing this review by (b) (4), for areas and (b) (4) that would be used during (b) (4). We would extend these learnings to other areas and (b) (4) as they are (b) (4).

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

We indicated we had replaced all ingredient hoppers with (b) (4) (b) (4). To confirm, we completed this work on April 21, 2015, and will maintain documentation on file at our Brenham facility. We will also include the hoppers on our master sanitation schedule, which is being reviewed in light of the modifications to the facility and equipment. We will ensure an updated master sanitation schedule is in place before we resume production.

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

We indicated we would update our good manufacturing practices (GMPs) to make clear that beard nets must be worn by employees with facial hair. Our updated GMPs are attached. (Attachment A). Moreover, we have developed a company-wide clothing and uniform policy that requires that employees with facial hair to wear beard nets in the Production, Ingredient Processing, Mix Processing, and Bakery areas of the plant. The policy includes illustrations demonstrating the proper way to wear to wear a beard net and the type of facial hair that requires a beard net to be worn. (Attachment B.) Employees will be retrained on GMPs and the new uniform policy before production resumes.

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

As explained, we cleaned, repaired, and repainted the ceiling vent above Blender (b) (4) on March 29, 2015. Supporting documentation will be maintained onsite at the Brenham facility. In addition, we stated we would examine all surfaces for chipped, cracked, or peeling paint and would make any necessary repairs. We anticipate completing that work by (b) (4), for areas in which (b) (4) with additional areas following as (b) (4).

We also indicated we would replace all (b) (4) with a (b) (4). We anticipate completing this work by (b) (4).

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

July 21, 2015

Blue Bell Creameries (Blue Bell or the Company) appreciates the opportunity to provide this update to the Food and Drug Administration (FDA) regarding corrective actions taken at our ice cream manufacturing facility in Broken Arrow, Oklahoma, in response to the FDA Form 483 Inspectional Observations (the 483) issued to our facility on May 1, 2015.[1] In our May 22, 2015, response to the 483, we outlined a number of corrective actions in response to FDA's observations and committed to providing an update on our corrective actions in 60 days. We thank FDA for allowing us the opportunity to provide this 60-day update.

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

This update identifies the current status of the corrective actions identified in our initial 483 response but not yet completed when that response was submitted. As we have explained to FDA, we plan to focus efforts on resuming production first at our facility in Sylacauga, Alabama. We therefore have devoted substantial attention to completing modifications to the equipment, infrastructure, and procedures for that facility. We plan to use what we learn in the process of bringing that facility back into operation to inform our approach to continued corrective actions in our Broken Arrow facility.

Although we have focused significant attention and resources on our facility in Sylacauga, we have not been idle in Broken Arrow. We have been hard at work cleaning and sanitizing equipment and the facility, including (b) (4) to allow for (b) (4). We have also been making numerous facility and infrastructure improvements not directly related to any Observation in the 483 but intended to enhance our ability to produce safe, wholesome ice cream at Broken Arrow. Because of these decisions, many of the detailed corrective actions identified in our 483 response remain to be completed. This is simply a matter of sequencing and prioritization. (b) (4), for example, so we have not had an opportunity to complete the modifications we intend to make when (b) (4). We identify in this update, to the extent possible, anticipated completion dates for these equipment modifications,

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but a number of variables—including our experiences with our other facilities—could cause these anticipated dates to shift.

Likewise, we have prioritized developing procedures and programs to support operations at our Sylacauga facility. Some of these procedures reflect company-wide programs. We identify such programs in this update. Other procedures are specific to operations at our Sylacauga facility but will translate to Broken Arrow operations with some amount of modifications. Because we do not (b) (4) we intend to wait to modify or finalize these latter procedures for our Broken Arrow facility until we gain more experience with them during (b) (4) at our Sylacauga facility. We fully intend to incorporate any learnings from these programs at our Sylacauga facility into the procedures we finalize for our Broken Arrow facility.

Moreover, although we do not plan to (b) (4) in the immediate future, it is our tentative plan, when ready, to begin (b) (4) (b) (4). To that end, we are prioritizing completing corrective actions that will affect the equipment and procedures required to (b) (4) (b) (4), with the intent to continue implementing corrective actions and modifications on (b) (4) before it is (b) (4).

We appreciate FDA's understanding of this complicated corrective action sequence and the (b) (4) (b) (4) to implementing corrective actions that results from it. We remain committed to providing FDA with updates on our progress at our Broken Arrow facility, and we plan to provide another update 60 days from today (120 days from our original 483 response) informing FDA of the status of the remaining corrective actions.

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

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

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

We committed to providing revised cleaning and sanitation procedures to FDA once the procedures are complete. We have focused our efforts company-wide on reviewing the cleaning and sanitation procedures that pertain to the equipment and processing lines we hope to bring back into operation first in our Sylacauga facility. Accordingly, we have not yet completed the review of cleaning and sanitation procedures (b) (4), although we fully intend to do so before (b) (4) (b) (4). As was our approach with our Sylacauga facility, we will first focus our attention on those cleaning and sanitation procedures necessary to support the (b) (4) (b) (4), and we will expand our review to include additional procedures as they become

necessary to support (b) (4). We anticipate using common cleaning and sanitation procedures across our facilities to the extent possible, and we will apply any learnings from our (b) (4) (b) (4) operations at our Sylacauga facility to our review of cleaning and sanitation procedures for our Broken Arrow facility. At this point, we cannot (b) (4) (b) (4), but we remain committed to keeping FDA informed of our efforts to review and modify as appropriate our cleaning and sanitation procedures for our Broken Arrow facility.

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

We indicated we would (b) (4) to the (b) (4) as well as install a (b) (4) our CIP and clean-out-of-place (COP) operations. We completed installation of the (b) (4) on July 15, 2015, and we are maintaining supporting documentation on file at our Broken Arrow facility. Although we had initially anticipated (b) (4) by the time of this update, changes to the corrective action sequence for Broken Arrow (b) (4). Once the equipment is installed, we will be able to install the (b) (4). We anticipate completing this work by (b) (4) (b) (4).

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

We identified various planned modifications in response to this Observation:

- Reconfigure pipe and line layout to minimize potential for condensation to come into contact with food or food contact surfaces. We anticipate completing this work by (b) (4) (b) (4), for areas and lines that would be used during (b) (4). We would continue addressing other areas and lines as (b) (4).
- Insulate pipes or install splash guards when reconfiguration is not feasible. We anticipate completing this work by (b) (4), for areas and lines that would be (b) (4) (b) (4). We would continue addressing other areas and (b) (4) as (b) (4) (b) (4). Further, because equipment is (b) (4) (b) (4), we may revisit the splash guards once the (b) (4) are configured.
- Add troughs under pipes to master sanitation schedule. We anticipate completing this work by (b) (4), for areas and lines that would be (b) (4) (b) (4). We would continue addressing other areas and lines as they are (b) (4) (b) (4).
- Evaluate gaskets to ensure proper fit and replace gaskets as needed. These gaskets are the seals around the (b) (4) on the (b) (4). We anticipate completing this work by (b) (4), for areas and (b) (4) that would be (b) (4) (b) (4). We would continue addressing other areas and (b) (4) as they are (b) (4) (b) (4)

- (b) (4) in production area. We plan to make this adjustment when we resume production. We are not currently in a position to project a specific date.
- Train employees on proper handling of equipment. We anticipate completing this training by September 1, 2015. The training will be conducted before production is resumed.
- Evaluate ways to adjust cleaning procedures to minimize likelihood that the (b) (4) (b) (4) could contaminate product. We plan to ensure all (b) (4) seals on the (b) (4) (b) (4) before the (b) (4) are (b) (4). We will train employees to clean the (b) (4) using (b) (4) rather than (b) (4) (b) (4) when appropriate. We anticipate completing this work by (b) (4), for areas and (b) (4) that would be used during (b) (4). We would continue addressing other areas and (b) (4) as they are (b) (4). We anticipate completing training by September 1, 2015.
- Modify flavor tanks (b) (4) and (b) (4) so that their lids are attached by hinges. As indicated in our initial response, we had completed this modification by the time we submitted our response on May 22, 2015. We have since (b) (4).
- (b) (4) machine. We explained in our initial response that we had (b) (4) (b) (4) machines. To confirm, we (b) (4). We do not (b) (4) (b) (4).
- (b) (4) filling machines. We anticipate completing this work by (b) (4), for areas and (b) (4) that would be (b) (4). We would continue addressing other areas and (b) (4) as they are (b) (4). We had initially anticipated this action being complete within (b) (4) days, but following our response, we decided to make additional infrastructure modifications that changed the timeline for this corrective action.
- Evaluating the feasibility of using non-metal components for parts of machines. We had originally anticipated completing this action within (b) (4) days, but we have since re-sequenced our corrective actions. We plan to complete this evaluation by (b) (4).
- Evaluate feasibility of using splash shield on (b) (4) fillers. We had originally anticipated completing this action within (b) (4) days, but we have since (b) (4) (b) (4) (b) (4).
- Reconfigure lines leading to filling machines. We anticipate completing this work by (b) (4), for areas and lines that would be used during an initial startup production. We would continue addressing other areas and lines as they are (b) (4) (b) (4).
- Move packaging equipment to allow staging of boxes not under pipes. We originally anticipated completing this action within (b) (4) days, but our subsequent changes to (b) (4) further infrastructure modifications have changed the timing for this action. We now anticipate completing this work by (b) (4), for areas and (b) (4) that would be used during (b) (4) as we (b) (4) the (b) (4) area. We would continue addressing other areas and (b) (4) as they are (b) (4) (b) (4).

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

We indicated we would revise our good manufacturing practices (GMPs) to reinforce proper employee handwashing and glove use. Our revised GMP Policy is attached. (Attachment A.)

We also committed to retraining employees before startup on topics including proper identification of food-contact surfaces and the importance of wearing proper attire. We anticipate completing that training by September 2015.

We also explained that we would institute a new company-wide clothing policy. The company-wide policy establishes general requirements and expectations and standardizes aspects such as smock and hairnet colors (to aid in managing traffic flow and hygienic zoning). Under the company-wide policy, all employees are required to show up for work in clean shirt and pants. Employees will be required to wear hairnets in the Production, Ingredient Processing, Mix Processing, (b) (4), and Bakery areas of the plant, with the hairnets color-coded to indicate whether the wearer is an employee working in a raw area, an employee working in another production area, or is a visitor, vendor, or contractor. Employees with facial hair will be required to wear beard nets. Employees and visitors, vendors, or contractors entering areas designated (b) (4) (Production, Ingredient Processing) will have to wear smocks over their uniforms. The smocks will be color coded to indicate whether the wearer is an employee working in that area, a maintenance employee, or a visitor, vendor, or contractor. The company-wide policy also includes a (b) (4) component: employees working in (b) (4) areas (Production, (b) (4), Ingredient Processing) must wear (b) (4) (b) (4) in those areas. Employees working in other areas of the plant who should have need to enter a (b) (4) area will be required to don shoe covers. A copy of the company-wide uniform program is included at Attachment B.

Finally, we indicated we would install (b) (4) at entrances to (b) (4) processing areas. We anticipate completing that work by (b) (4). We will maintain documentation for this action on file at our Broken Arrow facility.

Observation 7:

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

We indicated we would identify a permanent location for storing equipment that is not in use as well as a dedicated location for cleaning and sanitizing equipment coming on and off the line. We are in the process of (b) (4) in our facility that will be capable of (b) (4) (b) (4) (b) (4). Adjacent to this (b) (4) will be a dedicated space for drying, cleaning, and storing equipment. We anticipate completing this addition by (b) (4).

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

We explained that we would discontinue the use of (b) (4) in production and processing areas and that we would identify a replacement. We have elected to (b) (4) for these areas and plan to implement (b) (4). We anticipate completing this program by (b) (4).

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.

We have (b) (4) and closely inspected our equipment. As part of the (b) (4) process, we explained we would fully clean and sanitize all equipment before (b) (4) (b) (4). We have developed a procedure, attached, to ensure that all equipment is (b) (4) (b) (4) and carefully cleaned and sanitized before being (b) (4) (b) (4) the production areas. (Attachment C).

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

We explained that we would add the front face plate of (b) (4) freezer and their corresponding gaskets to our master cleaning schedule and that these components will be monitored in our routine sampling program. We will ensure the gaskets are added to the master sanitation schedule by (b) (4). We will add these components to the list of swab sites to be included in the environmental monitoring program for Broken Arrow. We are still finalizing the sample locations for this program and anticipate completing that process by (b) (4).