

Jeni's Splendid Ice Creams, LLC

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Mr. Stephen J. Rabe

Compliance Officer

United States Food and Drug Administration

Response to Form 483 Issued April 30, 2015

Mr. Heitkemper and Mr. Rabe,

On behalf of Jeni's Splendid Ice Creams, LLC, I would like to respond to the Form 483 that you issued following the recent facility inspection, and to provide additional information on the substantial improvements we have made to our food safety program.

GENERAL RESPONSE

Jeni's is committed to the safety of its customers. To that end, we have implemented new, systemic safety measures in response to the tests indicating the presence of listeria, in response to the Form 483 that the FDA recently issued, and to ensure that our manufacturing practices will be state-of-the-art when it comes to food safety. Elements of this systemic response include the following:

- 100% Recall – Although product testing only indicated the presence of listeria in limited numbers of batches and only in pint-size containers, Jeni's has recalled all frozen products; every flavor; every size, regardless of date of manufacture. None of the recalled product will be returned to commerce. None will be consumed.

- 100% Facility Shut-Down – Jeni’s has closed the only location where we made our products in order to correct any issues before producing the next batch for consumption.
- Facility Clean-Up – we retained the services of an expert, (b) (4) with (b) (4) to thoroughly clean and decontaminate our kitchens. This clean-up process has been completed.
- Review and Improvement of SOPs – we retained the services of (b) (4) of (b) (4) to provide Jeni’s with comprehensive food safety programs. His report on this subject is attached. Among other changes detailed here, we have completely reworked our sanitation efforts, deciding to outsource overnight breakdown and cleaning of all equipment and the facility, and require (b) (4) sampling of equipment prior to reassembly (b) (4)
- Staff Retraining – Jeni’s has re-trained its production staff, and has instructed them to follow (b) (4) hygiene and other protocols. The training has been lengthy and intensive, including multiple days for every employee at our home office and multiple days at our manufacturing plant. The training has been conducted by company leaders, by sanitation experts, including leaders from (b) (4) and by (b) (4) (b) (4)
- New QC Tech Team – We have built a team of Quality Techs that will be our eyes and ears on the floor during each shift. This team has been trained on (b) (4) protocols, environmental monitoring, pre-op inspections, and (b) (4) swabbing.
- Specialized Cleaning Services – an outside company that specializes in cleaning dairy equipment will clean and sanitize the entire facility, including all machinery, (b) (4) (b) (4). The company, (b) (4) is a recognized expert in these processes, and has been on-site with our team for more than a week. (b) (4) has performed a number of cleans already, and we believe the new protocols are working well.
- Physical Improvements – Jeni’s has renovated its kitchen, including by removing a wall (to expand the production space and improve traffic flow), and by removing or repairing various items. We expanded and reconfigured the cooler to increase its storage capacity and reduce traffic flow in and out of the cooler. We have also installed a barrier (an egress-only door) between the prep and shipping areas in order to discourage foot traffic between the areas, and to encourage staff to access the prep area from the break room instead of from shipping.
- Off-site Handling and Production – To ensure adequate workspace for core production activities, and to remove potential vectors of contamination, (b) (4) (b) (4) will now be processed at a separate location.
- Vendor Verifications – Jeni’s will require more robust documentation from its suppliers regarding their food safety programs and compliance with cGMP.
- Ongoing Testing for Pathogens – Jeni’s will conduct (b) (4) tests of its kitchen before reopening to verify the effectiveness of its clean-up efforts. Going forward, Jeni’s will routinely conduct (b) (4) testing of the kitchen. In addition, Jeni’s will implement

a (b) (4) protocol. (b) (4) will be tested for listeria, and will not be released into commerce unless and until it tests negative.

OBSERVATION 1

Responsibility for assuring compliance with current good manufacturing practices relating to personnel has not been assigned to competent supervisory personnel.

For example, the Regulatory Manager and the Director of Operations, who are responsible for assuring compliance with current good manufacturing practices by all personnel, demonstrated a lack of competency as evidenced by:

- A) Neither the Regulatory Manager nor the Director of Operations instituted an environmental sampling and testing program.
- B) Neither the Regulatory Manager nor the Director of Operations were aware that the employees on the p.m. shift were not sanitizing the food contact surfaces of the inside of the batch freezers at the end of the production day as required by your internal procedures.
- C) Neither the Regulatory Manager nor the Director of Operations were aware that the (b) (4) towels, which were being used as sanitizing wipes on food contact surfaces such as thermometers used in production and (b) (4) piston filler parts, did not actually contain any sanitizer.
- D) Neither the Regulatory Manager nor the Director of Operations were aware of the need to apply a sanitizer or disinfectant to the floors of the facility.
- E) The Regulatory Manager and the Director of Operations permitted employees to garden in the yard in front of the plant with no apparent controls or procedures in place to prevent contamination of your plant when employees return to work.

RESPONSE TO OBSERVATION 1

To bolster our on-site expertise regarding food safety, we have begun recruiting for (b) (4) new positions. Our plan is to assign these new employees the job titles of Quality Assurance Lead and Sanitarian.

Jeni's retained (b) (4) to review Jeni's current good manufacturing practices, to recommend improvements, and to retrain the production staff. (b) (4) report on these subjects (including new procedures) is attached. Staff has been retrained, through multiple-day training sessions, to follow the recommended procedures. These procedures will be implemented immediately upon restart of production.

We are maintaining the relationship with (b) (4) including additional assistance during startup and post-startup auditing.

- A) Jeni's has implemented, and will be following, new procedures for environmental sampling and testing.
- B) Staff has been retrained on new hygienic procedures, including a Master Cleaning Program SSOP that specifies, among other items, closing duties. In

addition, (b) (4) an outside company that specializes in cleaning dairy equipment will clean and sanitize the entire facility, including all machinery, (b) (4) (b) (4)

C) Staff has been retrained on new hygienic procedures, including a Master Cleaning Program SSOP that specifies, among other items, proper cleaning of food contact surfaces. In addition, (b) (4) an outside company that specializes in cleaning dairy equipment will clean and sanitize the entire facility, including all machinery, (b) (4)

D) Staff has been retrained on new hygienic procedures, including a Master Cleaning Program SSOP that specifies, among other items, proper cleaning of floors (b) (4) In addition, (b) (4) an outside company that specializes in cleaning dairy equipment will clean and sanitize the entire facility, including all machinery (b) (4)

E) Staff has been retrained on new hygienic procedures, including a Master Cleaning Program SSOP that specifies, among other items, numerous elements of personal hygiene.

OBSERVATION 2

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

For example, according to management you have not instituted an environmental monitoring and testing program or a finished product testing program at your plant though you routinely manufacture frozen ready-to-eat ice cream, yogurt, and sorbet.

RESPONSE TO OBSERVATION 2

Jeni's will perform (b) (4) testing of the facility before reopening.

On an ongoing basis, Jeni's will conduct (b) (4) testing of the production area and equipment. If a result is presumptive positive, the surface or equipment will be quarantined and subject to root cause analysis, and the schedule of testing will be intensified. These protocols will be implemented immediately upon the reopening of the production facility.

Immediately upon the reopening of the production facility, Jeni's will implement a (b) (4) (b) (4) protocol. (b) (4) will be tested for listeria, and will not be released into commerce unless and until it tests negative.

OBSERVATION 3

Failure to provide sufficient space for placement of equipment and storage of materials as necessary for the maintenance of sanitary operations and the production of safe food.

Specifically, there is insufficient space in the plant, including the prep and production rooms, to maintain an adequate flow of employees and equipment through the plant. For example, employees were observed re-routing foot and cart traffic due to other foot and cart traffic, and employees were observed bumping into each other in the ice cream

production room while attempting to perform their duties. In addition, the produce sinks are (b) (4) from the prep tables where open product is located, and the prep area hand wash sink is located (b) (4) from the same prep tables.

RESPONSE TO OBSERVATION 3

The production rooms have been renovated to ameliorate crowded conditions. We removed a wall to expand the production area and aid the traffic pattern. We installed a (b) (4) the freezer.

We expanded and reconfigured the cooler to increase its storage capacity and reduce traffic flow in and out of the cooler. We have also installed a barrier (an egress-only door) between a the prep and shipping areas in order to discourage foot traffic between the areas, and to encourage staff to access the prep area from the break room instead of from shipping.

To ensure adequate workspace for core production activities, and to remove potential vectors of contamination (b) (4) will now be processed at a separate location.

OBSERVATION 4

Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.

For example,

- A) According to management, you do not apply a sanitizer or disinfectant to the floors in your plant.
- B) On 4/2112015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, spilled ice cream base mix was observed on the floor of the large walk-in cooler around the cream transfer pump and the (b) (4) gallon black plastic cream tote.
- C) There are no door foamers, sanitizing mats, or other similar items in the three doorways to the prep area to protect the floors of the manufacturing areas from cross-contamination from foot, cart, and ice cream tote traffic.
- D) On 4/2112015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, a dark brown residue was observed adhering to the underside of the power outlet box on the west side of the evaporator unit located directly above the (b) (4) prep mix tables where employees prepare ingredients for use in manufacturing.
- E) On 4/2112015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, spots of a dark brown residue were observed adhering to the plastic light covers over the two ceiling lights located above the two prep mix tables where employees prepare ingredients for use in manufacturing.
- F) On 4/2112015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, a discolored piece of clear plastic was observed protruding out from the underside of a plastic grate over an unused air return

located in the ceiling above a metal wire shelving unit beside the two prep mix tables where employees prepare ingredients for use in manufacturing.

G) On 4/21/2015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, apparent dust and dirt was observed adhering to the cap and retaining wire on the fire sprinkler in the hood directly above the kettle referred to as "Aretha", which was used to prepare batches of base mix.

H) On 4/21/2015 during the manufacture of Jeni's brand The Buckeye State ice cream in pint size plastic containers lot number 5-111-288, a light brown material was observed adhering to the rectangular opening of the hose reel through which the water hose retracts above Batch Freezers C and D in the production room.

I) On 4/21/2015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, discolored vertical plastic strip curtains were observed in the doorway leading from the large walk-in cooler to the prep room and in the doorway leading from the walk-in freezer to the prep room. The large walk-in cooler was used for the refrigerated storage of ice cream base mixes and the walk-in freezer was used for the hardening and storage of finished product including ice cream.

RESPONSE TO OBSERVATION 4

Jeni's retained [REDACTED] (b) (4) to review Jeni's current good manufacturing practices, to recommend improvements, and to retrain the production staff. [REDACTED] (b) (4) report on these subjects (including new procedures) is attached. Staff has been retrained, through multiple-day training sessions, to follow the recommended procedures. These procedures will be implemented immediately upon restart of production.

The new protocols include an extensive Master Cleaning Program SSOP, which includes detailed instructions regarding cleaning duties every morning, mid-day, and closing, as well as weekly, monthly, and quarterly duties.

Foot foamers have been installed at designated locations, and portable foamers will be used during sanitation.

In addition, [REDACTED] (b) (4) an outside company that specializes in cleaning dairy equipment will clean and sanitize the entire facility, including all machinery. (b) (4)

OBSERVATION 5

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

For example, on 4/21/2015 during the manufacture of Jeni's brand The Buckeye State ice cream in pint size plastic containers lot number 5-111-288, two pieces of a white foam-type insulation were wrapped around the outside of the stainless steel hopper for the [REDACTED] (b) (4) piston filler and secured with clear packing tape such that there were gaps between the pieces of insulation. In addition, there were streaks and drips of apparent ice cream

adhering to the packing tape, insulation, and gaps between the insulation and product was observed leaking from the piston block, traveling down to the surface immediately next to the filling nozzle and dripping.

RESPONSE TO OBSERVATION 5

The hopper insulation and tape around the stainless steel hopper has been removed and discarded to allow proper cleaning and easier sanitation.

OBSERVATION 6

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

For example, the (b) (4) batch freezers each have an unsealed approximately 1/2 inch hole in the left corner of the control panel where a water hose was removed and an uncovered knob stem near the ice cream door where the water control knob was removed. Brown adhering material was observed on the edges of the hole and around the knob stem.

RESPONSE TO OBSERVATION 6

The holes and the uncovered knob stems have been sealed and covered with stainless steel caps to allow proper cleaning and easier sanitation.

OBSERVATION 7

Failure to store raw materials in a manner that protects against contamination.

For example, on 4/21/2015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, you stored white plastic bins containing the ingredients cocoa powder, sugar, and flour directly beneath the (b) (4) three compartment sinks located along the east wall of the prep room that are used for washing, rinsing, and sanitizing raw produce.

RESPONSE TO OBSERVATION 7

To ensure adequate workspace for core production activities, and to remove potential vectors of contamination, two significant changes have been made:

1. We have removed the sinks from the East Wall of the prep area.
2. (b) (4) will now be processed offsite

OBSERVATION 8

Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food and food-contact surfaces.

For example, on 4/21/2015, a heavy accumulation of apparent dust and dirt was observed adhering to the guards over the (b) (4) fans on the evaporator unit located in the dish room where tubs, equipment parts, and utensils used in production are washed, rinsed, sanitized, and stored.

RESPONSE TO OBSERVATION 8

Jeni's retained (b) (4) to review Jeni's current good manufacturing practices, to recommend improvements, and to retrain the production staff. (b) (4) report on these subjects (including new procedures) is attached. Staff has been retrained to follow the recommended procedures, which will be implemented immediately upon restart of production.

The new protocols include an extensive Master Cleaning Program SSOP, which includes detailed instructions regarding cleaning duties every morning, mid-day, and closing, as well as weekly, monthly, and quarterly duties.

In addition, an outside company that specializes in cleaning dairy equipment will clean and sanitize the entire facility, including all machinery. (b) (4)

OBSERVATION 9

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

For example,

A) For example, on 4/21/2015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, an employee dumped a (b) (4) paper bag of cocoa powder into the kettle referred to as "Aretha" such that the outside of the paper bag was in direct contact with the inner food contact surface of the kettle.

B) According to management, between every (b) (4) batches of base mix prepared in the kettle referred to as "Aretha" you turn off the kettle, add water needed for the next batch, and then allow it to sit for approximately (b) (4) before preparing the next batch. There is no cleaning step to remove residual product from the inside of the kettle before adding the water.

RESPONSE TO OBSERVATION 9

We are constructing a (b) (4) where bags of raw material will be opened and poured into containers to hold the raw materials. Once the (b) (4) is completed, outside packaging from these raw materials will no longer touch the kettles.

We have also changed our SOP's so that the kettles will be cleaned and sanitized after (b) (4) (b) (4) They will be cleaned after any batch that is (b) (4)

OBSERVATION 10

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

For example,

A) On 4/21/2015 during the manufacture of Jeni's brand The Buckeye State ice cream in pint size plastic containers lot number 5-111-288, an employee hung their apron on a metal wire shelf in the northwest corner of the prep room such that the apron strings were in direct contact with the prep room floor. In addition, an employee chef coat was lying directly on the floor under the apron.

B) On 4/21/2015 during the manufacture of Jeni's brand The Buckeye State ice cream in pint size plastic containers lot number 5-111-288, an employee stored their chef coat over an orange-colored concrete post located on the east side of the sliding door leading from the prep room to the dry storage area. The surface of the post was rough and had some chipped paint.

RESPONSE TO OBSERVATION 10

Company policies were such that chef coats were not supposed to be found in the areas where they were observed. We have updated our policies to ensure that the rules are clearer and have retrained all manufacturing employees on these policies. In addition, we have created a team of QC Techs that have been trained on these procedures and have been instructed to enforce these rules on every shift and to ensure compliance by the employees.

Jeni's retained (b) (4) to review Jeni's current good manufacturing practices, to recommend improvements, and to retrain the production staff. (b) (4) report on these subjects (including new procedures) is attached. Staff has been retrained to follow the recommended procedures, which will be implemented immediately upon restart of production.

Staff has been retrained on new hygienic procedures, including a Master Cleaning Program SSOP that specifies, among other items, numerous elements of personal hygiene.

OBSERVATION 11

Failure to perform filling and packaging in a manner that protects food from becoming contaminated.

For example, on 4/21/2015, the employee using the (b) (4) piston filler was observed filling plastic pints of Jeni's brand The Buckeye State ice cream lot 5-111-288 even with or above the top rim of the plastic pint, before applying the snap-on cap, causing product to overflow the sealing surface of the container and flow under the rim. In addition, finished frozen pints of Jeni's brand The Buckeye State ice cream lot 5-111-288 and finished frozen pints of Jeni's brand Savannah Buttermint ice cream lot 5-110-265 were observed to be similarly overfilled.

RESPONSE TO OBSERVATION 11

Similar to observation 10, what was observed was counter to Jeni's pre-existing policies. The QC Tech team that we created, along with our leads and manufacturing leadership, will be responsible to ensure that we are not overfilling pints during production.

Beyond that, we are changing our pint manufacturing significantly. First, we are changing to a more-standard, (b) (4) We will be (b) (4)

equipment. As we recommission the facility initially, we will not immediately resume the manufacture of manufacturing pints. Before we do so, we will ensure that employees receive the appropriate training on the proper fill levels/techniques/processes, the machines are properly calibrated and over-filling is not an issue. And, as previously noted, we have provided updated GMP training to all employees. We have trained the machine operators on machine assembly and disassembly.

CONCLUDING REMARKS

In the last couple of days we have invited the Ohio Department of Agriculture in for an informal walk-through and made changes consistent with their suggestions. Later today, the ODA will formally inspect the facility. When the ODA and our leadership team is convinced we are prepared to operate the facility at or beyond all federal and state requirements, we will recommission the facility and begin producing ice cream again. We believe that will occur tomorrow, Wednesday, May 13, 2015. As always, we remain open to inspection, suggestion, feedback and comment from the FDA and the ODA. We appreciate the professionalism of the staff with whom we have interacted, and the help they have provided. Similarly, we hope that the FDA staff sees a company singularly focused on getting its facility, facility leadership, training, and processes right.

Sincerely,

John Lowe
CEO

Courtesy copies via email:

Inspector Matthew B. Casale
Inspector Darren S. Morgan
Inspector Craig P. Seaborn