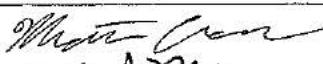
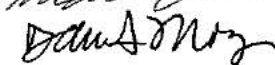
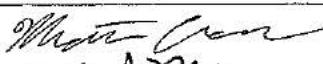
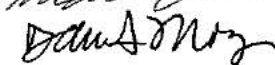
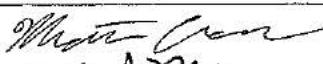
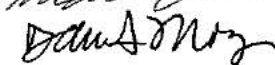
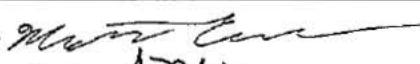
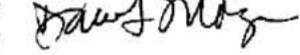
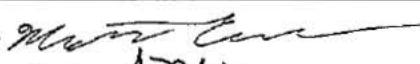
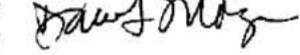
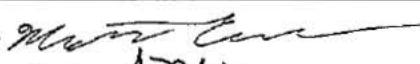
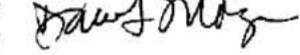
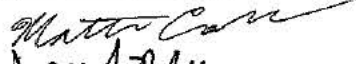
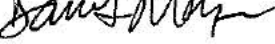


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 (513) 679-2700 Fax: (513) 679-2772 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 04/20/2015 - 04/30/2015* FEI NUMBER 3008586462
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED TO: John (nmi) Lowe IV, President and CEO		
FIRM NAME Jeni's Splendid Ice Creams, LLC	STREET ADDRESS 909 Michigan Ave	
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43215-1108	TYPE ESTABLISHMENT INSPECTED Food Manufacturer	
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>		
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>Responsibility for assuring compliance with current good manufacturing practices relating to personnel has not been assigned to competent supervisory personnel.</p> <p>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:</p> <ul style="list-style-type: none"> 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) 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. 		
<p>OBSERVATION 2</p> <p>Failure to perform microbial testing where necessary to identify sanitation failures and possible food contamination.</p> <p>For example, according to management you have not instituted an environmental monitoring and testing program or a</p>		
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<p>finished product testing program at your plant though you routinely manufacture frozen ready-to-eat ice cream, yogurt, and sorbet.</p>							
<p>OBSERVATION 3</p> <p>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.</p> <p>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) from the prep tables where open product is located, and the prep area hand wash sink is located (b) from the same prep tables.</p>							
<p>OBSERVATION 4</p> <p>Failure to maintain buildings, fixtures, or other physical facilities in a sanitary condition.</p> <p>For example,</p> <ul style="list-style-type: none"> A) According to management, you do not apply a sanitizer or disinfectant to the floors in your plant. B) On 4/21/2015 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) 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 4/21/2015 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 two prep mix tables where employees prepare ingredients for use in manufacturing. E) On 4/21/2015 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 4/21/2015 during the manufacture of various batches of base mix for Jeni's brand Dark Chocolate ice cream, a 							
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<p>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 (b) (4) prep mix tables where employees prepare ingredients for use in manufacturing.</p> <p>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.</p> <p>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.</p> <p>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.</p>					
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 (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, travelling down to the surface immediately next to the filling nozzle and dripping.					
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.					
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OBSERVATION 7 <p>Failure to store raw materials in a manner that protects against contamination.</p> <p>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.</p>					
OBSERVATION 8 <p>Failure to operate fans and other air-blowing equipment in a manner that minimizes the potential for contaminating food and food-contact surfaces.</p> <p>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.</p>					
OBSERVATION 9 <p>All reasonable precautions are not taken to ensure that production procedures do not contribute contamination from any source.</p> <p>For example,</p> <ul style="list-style-type: none"> 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. 					
OBSERVATION 10 <p>Suitable outer garments are not worn that protect against contamination of food, food contact surfaces, and food packaging materials.</p> <p>For example,</p>					
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<p>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.</p> <p>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.</p>			
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.			
* DATES OF INSPECTION: 04/20/2015(Mon), 04/21/2015(Tue), 04/22/2015(Wed), 04/23/2015(Thu), 04/24/2015(Fri), 04/27/2015(Mon), 04/28/2015(Tue), 04/30/2015(Thu)			
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."