

**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		DATE(S) OF INSPECTION 06/24/2008 - 06/27/2008
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED <b>TO: Jennifer L. Britton, Partner</b>		FEI NUMBER 3006737348
FIRM NAME Jeni's Splendid Ice Creams	STREET ADDRESS 1145 Chesapeake Ave Ste E	
CITY, STATE, ZIP CODE, COUNTRY Columbus, OH 43212-2286	TYPE ESTABLISHMENT INSPECTED Manufacturer	

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.

**DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:**

**OBSERVATION 1**

Effective measures are not being taken to exclude pests from the processing areas.

Specifically, rodent excreta pellets (REP's) were observed in the following areas:

- a) in the production area I observed approximately 3-4 REP's per foot along the oven wall for approximately six feet,
- b) in the dry food product storage area I observed approximately 22 REP's on Styrofoam shipping components adjacent to a food product,
- c) in the dry food product storage area I observed approximately 18 REP's in a box of unlabeled jars of fig almond paste on a shelf adjacent to the Styrofoam shipping components,
- d) in the floor wall junctures throughout the storage areas I observed numerous REP's.

Also I observed a live rodent on a glue trap next to the cleaning supply room door in the storage area.

Also there were 2-3 insects on each of three glue boards in the storage areas.

**OBSERVATION 2**

Failure to provide adequate screening or other protection against pests.

Specifically, there are numerous holes in the exterior wall of the facility with out screening to prevent pest access into the facility. For example I observed:

- a) an approximately 1/2" gap under both garage bay doors. In addition the bay doors were left open at various times throughout the inspection for periods of greater than one hour,
- b) two unscreened holes (approximately 4" and 1.5"), an approximately 1/4" gap around an approximately one inch pipe, and an approximately 18" X 18" exhaust fan in the east exterior wall near the roof access ladder,
- c) four holes in the in the west concrete wall that is shared with the adjacent facility. These holes are approximately 2" round, 3" round, 6" X 8", and 16" X 24".

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	PREVIOUS EDITION OBSOLETE	

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**OBSERVATION 3**

Employees in contact with food-contact surfaces and food-packaging materials were not maintaining adequate personal cleanliness.

Specifically, on 6/24/08 at approximately 9:05 am I observed an employee scratching his head with his bare hands and going back to work preparing the ice cream mix without washing his hands. Also other employees were observed leaving the production area with gloves on to retrieve boxes of ingredients and returning to work packaging ice cream into pints without washing their hands and/or replacing gloves.

**OBSERVATION 4**

Plumbing constitutes a source of contamination to food and equipment.

Specifically, the (b) hose attached to the hose bib next to the mixers is not of food grade material and an employee was observed using it to rinse the (b) (4) ice cream mixer.

**OBSERVATION 5**

Storage or use of toxic materials which are not required to maintain clean and sanitary conditions, are unnecessary for use in laboratory testing procedures, are unnecessary for plant and equipment maintenance, and are unnecessary for use in plant operations.

For example, on 6/24/08 I observed a quart sized can of acetone stored on the bottom of the ingredient storage shelf adjacent to food ingredients.

**OBSERVATION 6**

Employees were observed to be drinking beverages in areas where food is exposed and equipment or utensils are washed.

Specifically, on 6/24/08, I observed a production employee drinking from a can of tea in the production area. In addition to the can of tea, a bottle of water, and a drink cup with lid and straw were observed under the table where ice cream is packaged into pint containers.

On 6/25/08, I observed an employee drinking from a bottle of water in the production room.

Furthermore, employees personal food and drinks were being stored in the walk in refrigerator.

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*Deby Owen*

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**OBSERVATION 7**

Failure to wear beard covers and hair restraints where appropriate.

Specifically, I observed employees wearing ball caps ineffectively in that hair was protruding from underneath the ball cap over the exposed ice cream.

Also two employees with beards were observed not wearing beard covers during the production and packaging of ice cream.

**OBSERVATION 8**

Lack of backflow protection from piping systems that discharge waste water and sewage.

Specifically, there is no backflow protection device on the hose bib that is connected to the hose used for cleaning the mixer. The nozzle end of this is routinely stored in or on a drain pipe.

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FDA EMPLOYEES' NAMES, TITLES, AND SIGNATURES:



Christian L. Witkovskie, Investigator



Dell S. Moller, Investigator

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