

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

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| DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 1500 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187 Industry Information: www.fda.gov/oc/industry | DATE(S) OF INSPECTION 12/04/2008 - 01/08/2009* |
| | FEI NUMBER 1000115118 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
TO: Ms. Dorothy L. De La Torre, General manager

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| FIRM NAME Del Rey Tortilleria, Inc. | STREET ADDRESS 5201 W Grand Ave |
| CITY, STATE, ZIP CODE, COUNTRY Chicago, IL 60639-3007 | 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

Failure to properly store toxic cleaning compounds and sanitizing agents in a manner that protects against contamination of food and food-contact surfaces.

Specifically,

On 12/04/08 a heavy duty cleanser (b) (4) being stored in the room where tostadas are cooked and prepared tamales dough is mixed.

On 01/08/09 (b) (4) was being stored and accessible for use in the tortilla production area approximately 15' from where flour tortillas were being manufactured.

OBSERVATION 2

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

Specifically,

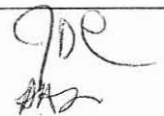
On 12/4/08, condensate like liquid was directly over stainless steel cooking tubs used to hold and store cooked and in process masa in the masa production area of the facility.

OBSERVATION 3

Failure to manufacture, package, and store foods under conditions and controls necessary to minimize contamination.

Specifically,

On 12/04/08, a medical inhaler was stored on the production table approximately 5' from the tortilla mixer in the production area of the firm.

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| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE Joseph D. Cooper, Investigator Rosemary A. Sexton, Acting Compliance Officer |  | DATE ISSUED 01/08/2009 |
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On 12/04/08, a hose used in the production of flour tortillas was on the floor in a pool of standing water just prior to being used to clean and sanitize the flour tortilla mixer in the production area.

On 12/4/08, an open drum labeled (b) (4) containing paint was stored in the firm's storage area directly next to the production area where the firm was manufacturing flour tortilla products. The drum was approximately 100' from tortilla production.

On 12/4/08, 2 large stainless steel spatulas were being stored directly on the floor. One spatula was being used in prepared dough for tamales in the Tostada room. The second spatula was on the floor just outside the door from where the masa production.

On 12/04/08, a plastic scoop used in masa production was laying directly on the equipment used to grind cleaned corn into masa. A similar scoop was in the chip manufacturing room being stored on top of a piece of cardboard and under several floor tiles.

On 12/4/08, an empty (b) (4) detergent bucket filled with hot water was used as an employee hand dip during masa production in the masa production room.

On 12/4/08, an empty (b) (4) detergent bucket was used as a corn strainer for masa production in the masa production area of the firm.

On 12/4/08, the firm's waste separator was leaking onto the floor in the storage area. Employees were observed walking to and from different storage and production areas of the firm conducting different tasks throughout the facility including in the production area.

OBSERVATION 4

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

Specifically,

On 12/04/08, three (3) dirty box fans used to cool, hot Tostadas was along the tostada cooling line. These fans had a build up of grease and dirt like substance on the blades of the fan and the cover of the fans and were blowing directly on to the tostadas.

THIS IS A REPEAT OBSERVATION

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| | <i>(Handwritten signatures: JDC, RAS)</i> | |

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*** DATES OF INSPECTION:**
12/04/2008(Thu), 12/18/2008(Thu), 01/08/2009(Thu)

Joseph D. Cooper Investigator
Rosemary A. Sexton, Acting Compliance Officer

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| | Joseph D. Cooper, Investigator Rosemary A. Sexton, Acting Compliance Officer | <i>JDC</i> <i>RAS</i> 01/08/2009 |