

**Establishment Inspection Report**  
Del Rey Tortilleria, Inc.  
Chicago, IL 60639-3007

FEI: 1000115118  
EI Start: 08/16/2004  
EI End: 09/03/2004

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**SUMMARY (JDC)**

This inspection of Del Rey Tortilleria, Inc. was conducted in accordance with CP 7303.803 (Domestic Food Safety FY'04) and as compliance follow up (FACTS # 557839) to verify voluntary corrections made since the previous inspection. This inspection was also a proactive measure for the upcoming school year, following last years Food Borne Outbreak among school children in Lawrence, MA.

Del Rey Tortilleria, Inc. is a bakery that manufactures flour tortillas and corn tortilla products. The firm has two other manufacturing locations at 1023 W. 18<sup>th</sup> Street Chicago, IL and 2701 S. Trumbell Chicago IL. The 18<sup>th</sup> Street location and the Trumbell street location only manufacture corn tortilla products. All Del Rey flour tortillas are manufactured at the 5201 W Grand Avenue Chicago IL 60639 location. We observed the production of;

- 12oz flour tortillas
- 15 oz flour tortillas(fajita size)
- 27 oz flour tortilla(Burrito # 2)
- 34 oz flour tortilla(Burrito # 3)
- Hot Mexican Chips
- 5 oz corn tostadas

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The previous inspection revealed GMP deficiencies and an 18 point FDA-483 was issued to Ms. Marcellina M. Toledo, General Manager of the firm at the close of the inspection. Objectionable observations noted on the FDA-483 included: using an algaecide as a sanitizer, improper storage of toxic compounds (REPEAT OBS), improper raw ingredient storage (REPEAT OBS), and lack of employee training.

The current inspection revealed GMP deficiencies and a 9-point FDA 483(Objectionable observations) was issued to Eduardo M. Pachero, accountant who was the most responsible person at the firm during the close out. Several of these observations were repeats from the previous inspection. The objectionable observations listed on the FDA 483 are;

- Adequate screening not being taken to exclude pests.
- Lack of adequate sewer drainage of areas that store foods.
- Failure to hold ingredients in suitable containers.
- Failure to operate fans in a way that minimizes contamination.
- Failure to properly hold and store toxic cleaning compounds.
- Failure to store raw materials properly.
- Failure to properly store equipment, remove litter and waste and other harborage or breeding grounds for pests.
- Ceilings are not kept in good repair.

On 8/16/2004, investigators Joseph D. Cooper and Ana L. Kewes displayed our credentials and issued a FDA 482 (Notice of Inspection) to Marcellina M. Toledo, plant manager. During this inspection we verified that the corrections have been made since the last inspection.

Insect-like activity was observed in the food warehouse area of the plant.

Rodent activity was observed in the food storage warehouse.

No avian-like evidence or refusals were encountered during this inspection.

Official Samples of flour tortillas were collected on 8/16/04 and 8/20/04 (270807-10) these samples were sent to CFSAN-LABS for food additive analysis. Surveillance Samples was collected on 8/20/04 for the CHI-DO FY'04 performance goals and work plan. PAC's 04004A (pesticides and industrial chemicals in domestic foods) and 07001 (mycotoxins in domestic foods).

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**FMD-145**

Ms. Marcellina M. Toledo, Plant Manager  
Del Rey Tortilleria, Inc.  
5201 West Grand Avenue  
Chicago, IL 60639

**ADMINISTRATIVE DATA**

Inspected firm: Del Rey Tortilleria, Inc.  
Location: 5201 W Grand Ave  
Chicago, IL 60639-3007  
Phone: 773-637-8900  
FAX: 773-637-5195  
Mailing address: 5201 W Grand Ave  
Chicago, IL 60639-3007

Dates of inspection: 8/16/2004, 8/20/2004, 8/27/2004, 9/3/2004  
Days in the facility: 4  
Participants: Joseph D. Cooper, Investigator  
Ana L. Kewes, Investigator

**HISTORY (JDC)**

Del Rey Tortilleria, Inc. is a three-story brick building with the entire manufacturing and packaging operations taking place on the first floor; the second and third floors are vacant. Del Rey has been in business for over 40 years and employees [REDACTED] full time employees. The plant is a [REDACTED] square foot bakery that manufactures tortillas and corn tortilla products. The bakery is located at 5201 W Grand Avenue Chicago, IL and has two other manufacturing locations at 1023 W. 18<sup>th</sup> Street Chicago, IL and 2701 S. Trumbull Chicago IL. The firm office operates 9a-5p Monday through Friday and from 8a-1p on Saturdays. Product is manufactured from 6a-6p Monday through Friday. Ms. Marcellina Toledo and Mr. Raul Garcia stated a thorough cleaning of the plant is conducted every Saturday. The Del Rey retail store operates 6a-6p, Monday through Sunday. Ms. Toledo informed me that the firm generates annual sales varying between \$ [REDACTED] and \$ [REDACTED] and that all training is conducted "hands on" at the firm.

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**INTERSTATE COMMERCE/JURISDICTION (JDC)**

Ms. Toledo stated that Del Rey Tortilleria, Inc. owns [redacted] trucks that distribute locally. Ms. Toledo also informed us approximately [redacted] of flour tortillas and [redacted] of all products manufactured at Del Rey Tortilleria, Inc. is shipped in interstate commerce. Del Rey produces flour tortillas and corn tortilla and other corn bases food products.

**RESPONSIBILITY (JDC)**

*Ms. Marcellina (Marcy) M. Toledo, General Manager*, stated that she was the most responsible individual at the firm at the time of inspection. Ms. Toledo also stated she is responsible for and has knowledge of all day-to-day operations, safety/quality, development, receiving raw material, hiring / firing powers and facility inspections. Ms. Toledo stated she works at the other two Del Rey facilities, but is currently in charge at the 5201 W Grand Avenue facility. I witnessed Ms. Toledo giving directions to employees to perform specific tasks. Ms. Toledo reports to her mother, *Jeanette A. Toledo, President*, who is the owner of Del Rey Tortilleria, Inc.

*Mr. Raul Garcia, Production Manager*, reports to Marcellina Toledo. Mr. Garcia handles all the production lines and its employees. Mr. Garcia states that he works about six times a week. The line employees report to him. Any problems that occur with machines on the line are reported to him.

*Mr. Eduardo Pacheco, Accountant*, reports to Marcellina Toledo. According to Mr. Pacheco, he is responsible for the firm's sales records. During the close out of the inspection we discussed our objectionable observations with Mr. Pacheco. He also facilitated the voluntary destruction of various dry peppers that were infested with insects. Mr. Pacheco stated that he cannot understand English that well, therefore Investigator Ana L. Kewes translated for us. Mr. Pacheco has worked for the Del Rey Tortilleria for about 15 years.

*Ms. Jeanette A. Toledo, President*, Del Rey Tortilleria, Inc. Ms. Marcy Toledo stated Ms. Jeanette Toledo is president and owner of all three Del Rey Tortilleria, Inc. facilities located at 5201 West Grand Avenue, 2701 S. Trumbull Avenue and 1023 West 18<sup>th</sup> Street Chicago, IL. Ms. Janet Toledo has been with the company for over 45 years. Ms. Janet Toledo was not available for the FDA inspection. According to Marcellina Toledo, [redacted]

**OPERATIONS, PERSONNEL, AND EQUIPMENT (JDC)**

Del Rey Tortilleria, Inc. is a manufacturer and distributor of tortillas and corn tortilla products. A list of consignees is attached as **Exhibit # 1**. The firm's hours of operation are Monday-Friday; 6a-6p. Ms. Toledo stated that Del Rey Tortilleria, Inc. owns [redacted] trucks that distribute locally. Ms. Toledo also informed us approximately [redacted] % of flour tortillas and [redacted] % of all products manufactured at Del Rey Tortilleria, Inc. is shipped in interstate commerce. Ms. Toledo informed us that the firm generates annual sales varying between \$ [redacted] and \$ [redacted] and that all training is conducted "hands on" at the firm.

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**PRODUCTS (JDC)**

Del Rey is a manufacturer of flour and corn tortillas. They also have numerous corn based snacks and dry peppers for seasonings. For a complete product list see exhibit # 12.

**MANUFACTURING CODES (JDC)**

Del Rey's flour tortilla packages are marked with a 45-day expiration date if the tortillas were made between, August 1<sup>st</sup> thru April 1<sup>st</sup>. On the final day of the inspection we noticed the following date codes for production on September 3<sup>rd</sup> 2004;

- 8" Flour tortillas had a "use thru date" of Nov 1 2004
- 6" Flour tortillas had a "use thru date" of Oct 18 2004
- Burritos # 2 had a "use thru date" of Dec 02 2004
- Burritos # 3 had a "use thru date" of Oct 18 2004

*90 days*

**OBJECTIONABLE CONDITIONS (JDC)****Observations listed on form FDA 483**

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**OBSERVATION 1**

Effective measures are not being taken to protect against the contamination of food on the premises by pests.

Specifically,

On 8/16/04 I (ALK) saw one dead roach in the food warehouse and another dead roach in the tostada production area.

On 8/27/04 we observed various insects at different stages of life, (larvae, pupae, and adult) on and around a pallet of wide dry peppers (ancho) being held in your food storage warehouse.

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Reference: 21 CFR 110.35(c)

**Relevance:**

Building and facilities in the manufacturing area of food products should be maintained to assure food quality and safety and to eliminate adulteration of food products. Food processing area should be free of pests to assure food quality and safety and to eliminate adulteration of food products.

**Discussion with management:**

Ms. Toledo voluntarily destroyed a pallet of dry peppers which were infested with insects on 9/3/04. She stated that the firm would perform visual checks of incoming products.

**Related samples and exhibits:**

See exhibit # 14 photo # 2

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**OBSERVATION 2**

Lack of adequate drainage of areas which may contribute to contamination of food by seepage, foot-borne filth, and providing a breeding place for pests.

**Specifically,**

In the food warehouse there is a storm sewer on the floor through which sewage water backs up into the warehouse when it rains. The floor is never washed and sanitized after such sewage back up flooding occurs.

Reference: 21 CFR 110.20(a)(3)

**Relevance:**

There is a possibility of cross contamination from dried sewerage on the floors of the warehouse. Since the floors are not cleaned and sanitized after the sewers back up, the substances can be brought into the production area by man or machine with the potential to become airborne.

**Discussion with management:**

Ms. Toledo has hired a contractor to repair her sewer drains and we observed work being done on the firms sewers on 8/27/04.

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Related samples and exhibits:

See Exhibit # 14 photos; 3, 4, 5, 6, 7, 8, and 9

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**OBSERVATION 3**

Failure to hold raw materials and ingredients in bulk or in suitable containers so as to protect against contamination.

Specifically,

We observed raw materials being stored in 5 gal paint buckets;

- On 8/16/04 we observed six, 5 gallon buckets of [REDACTED] at the base of the dough mixer in the flour tortilla production area.
- On 8/16/04 we observed two, 5 gallon buckets of unidentified raw materials on the floor of the flour tortilla production area.

**This is a repeat violation.**

Reference: 21 CFR 110.80(a)(5)

Relevance:

In-process raw ingredients should be maintained in a manner in which to assure food product safety and avoid contamination. These containers are not "Food Grade" material.

Discussion with management:

Ms. Toledo stated that she will purchase new containers for the firm. When she purchased these containers she assumed that because the advertisement stated "FDA Approved" that these containers were safe for food usage.

Related samples and exhibits:

See Exhibit # 14 photos 10, 11, & 15

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**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 8/16/2004 we observed dirty box fans used to cool hot ready to eat tostadas. These fans had a build up grease and a dirt-like material on the blades and grill of the fans.

**This is a repeat violation.**

Reference: 21 CFR 110.20(b)(6)

Relevance: Cooling fans should be maintained and kept clean to assure food quality and safety and to eliminate adulteration of food products.

Discussion with management:

Ms. Toledo stated that the firm cleans the fans before production every day, but now she will implement a cleaning of the fans several times daily as needed.

Related samples and exhibits:

See Exhibit # 14 photo #'s 12, 13, & 14

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**OBSERVATION 5**

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

Specifically,

On 8/16/04 we observed;

- One unlabeled spray bottle

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- One square gallon metal container (unlabeled)
- One can of [REDACTED] lubricant

These three containers were on the tortilla chip packaging machine in the chip production room.

**This is a repeat violation.**

Reference: 21 CFR 110.35(b)(2)

**Relevance:**

Cleaning products and other chemicals should be stored in an area of the firm to avoid possible contamination of food products.

**Discussion with management:**

Ms. Toledo stated she would talk to her employees about their work practices.

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**OBSERVATION 6**

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

Specifically,

On 8/16/2004 we observed the following conditions;

- An unlabeled container of Paprika in the tortilla chip processing room.
- An unlabeled container of Salt in the tortilla chip processing room.
- An unlabeled container of [REDACTED] was observed in the flour tortilla processing area.

On 8/20/04 I (JDC) observed

- Two unlabeled containers of raw materials in the flour tortilla processing area.

**This is a repeat violation.**

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Reference: 21 CFR 110.80(a)(1)

**Relevance:**

In process raw ingredients should be maintained in a manner in which to ensure food product safety and avoid contamination.

**Discussion with management:**

Ms. Toledo stated she would address these issues with management to make sure the production employees are following procedures.

**Related samples and exhibits:**

See exhibit # 14 photos 11 & 15

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**OBSERVATION 7**

Failure to provide adequate screening or other protection against pests.

Specifically,

(ALK) All the dock doors are kept wide open therefore allowing pests inside the facility at any time.

On 8/16/04 I, (ALK) observed several rodent-like pellets on the floor of a small room inside of the processing office located in the north east corner of the flour tortilla production area.

**This is a repeat violation.**

Reference: 21 CFR 110.20(b)(7)

**Relevance:**

Food processing areas should be free of pests to ensure food quality and safety and to eliminate the possibility of adulteration of food products.

**Discussion with management:**

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Ms. Toledo stated that she constantly has to remind her employees to close the dock doors and screens to keep pests out. She stated she would re-train her employees.

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**OBSERVATION 8**

Failure to properly store equipment, remove litter and waste, and cut weeds or grass that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures.

Specifically,

On 8/16/04 I (ALK) observed a large number of old and unused equipment as well as a large amount of wooden pallets piled up high right outside the dock door leading to the food warehouse at the firm. There are also a fair number of weeds growing along the south side of the building.

Reference: 21 CFR 110.20(a)(1)

Relevance:

The facilities must be kept clean and free of attractants to minimize the potential for pest harborage or breeding places.

Discussion with management:

Ms. Toledo had all pallets stacked outside removed by the second day of the inspection. (8/20/04)

Related samples and exhibits:

See Exhibit # 14 photo # 16

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**OBSERVATION 9**

The plant is not constructed in such a manner as to allow floors and ceilings to be adequately cleaned and kept clean and kept in good repair.

Specifically,

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On 8/27/04, we observed various ceiling panels broken and /or missing in the food storage warehouse.

Reference: 21 CFR 110.20(b)(4)

**Relevance:**

Food is stored directly under the broken ceiling tiles. If the ceiling begins to leak then the food stored directly beneath the ceiling can become contaminated.

**Discussion with management:**

Ms. Toledo stated that she has already begun to replace some of the broken ceiling panels.

**Related samples and exhibits:**

See Exhibit # 14 photos 17, 18, 19, & 20

**REFUSALS (JDC)**

No refusals were encountered on the inspection.

**GENERAL DISCUSSION WITH MANAGEMENT (ALK)**

On 9/3/04 I telephoned Mrs. Toledo to inform her that we would be at the firm that morning to issue the FDA-483 and close the inspection with her. Mrs. Toledo told me that morning that she felt indisposed and would not be at work that day. She also asked me to please close the inspection with Mr. Eduardo M. Pacheco, her accountant.

The FDA-483 had 9 observational points. Five of those points are repeat violations. Mr. Pacheco had no answer as to why the problems seem to persist rather than being resolved as management has stated in several letters sent to FDA promising or assuring that the firm's management either has already taken care of the problem or it is already in the process of fixing the problem or issue. Mr. Pacheco seemed sincere when he told me that he thought that the problems were very serious and he stated that he would personally talk with Mrs. Toledo and stress to her the importance of making positive and lasting changes at the firm. I also urged him to convey to Mrs. Toledo the importance of sending a response letter to our District addressing each FDA-483 points.

During the closeout I asked Mr. Pacheco why there was packaged product in the production area with different expiration dates and who was purchasing some unlabeled product also in the production area being ready to be shipped out.


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We saw the following product ready for shipment in the production area:

- 6" flour tortillas in bulk weighing 34 lbs wrapped in plain plastic bag. This product was packaged in a "Del Rey" cardboard case with the production date (9/3/04) and nutrition label attached to the case. This product was being sent to [REDACTED]
- 8" flour tortillas packaged in plain plastic bags (12 per bag) with expiration date of November 1, 04. This product is being shipped to [REDACTED]
- We saw more product with different expiration dates as follows:
  - October 18, 04
  - November 1, 04
  - December 2, 04

Mr. Raul Garcia, production supervisor told me that the recipe for the tortillas changes according to what the customer wants. ~~Therefore, the amount of calcium propionate is not constant for the different formulations used to make the tortillas. This information does not coincide with the information Mrs. Toledo had told us on 8/16/04.~~ On this date Mrs. Toledo told us that they had decreased the amount of calcium propionate in the formulation to [REDACTED] per [REDACTED] of flour (%) and with a shelf life of 45 days during the summer and 90 days in the winter time. 

Another fact we discovered during our closeout was that the unlabeled product is being sold to [REDACTED] a firm that supplies [REDACTED] restaurants. Mrs. Toledo has repeatedly told us that no more unlabeled product is being sold to anyone now that [REDACTED] is no longer their customer.

At the conclusion of our inspection, Mr. Pacheco told us that he would relay all the information to Mrs. Toledo and that he would urge her to make the necessary changes to comply with our observations.

**VOLUNTARY CORRECTIONS (JDC)**Corrections from the last inspection were:

- Del Rey no longer handles the algicide.
- New training procedures involving employee practices went into effect on 7/1/2004. This included keeping doors and screens closed as much as possible and the use of the yellow floor soap.
- All containers for ingredients are individually labeled, covered, and properly stored.
- [REDACTED] ingredient is properly labeled and covered.
- Piping on corn hopper was corrected.
- Three compartment faucets has air gap now.
- Hoppers are cleaned before and after production.
- Mixers are cleaned before and after production.
- Cooling racks are cleaned before and after production.