

Establishment Inspection Report

Del Rey Tortilleria, Inc.
Chicago, IL 60639

FEI: 1000115118
EI Start: 04/24/2009
EI End: 04/24/2009

TABLE OF CONTENTS

Summary 1
Administrative Data 2
History..... 3
Jurisdiction..... 4
Individual Responsibility and Persons Interviewed..... 4
Firm's Training Program 4
Manufacturing/Design Operations..... 5
Manufacturing Codes..... 6
Refusals..... 6
Additional Information 6
Exhibits Collected..... 6
Attachments 6

SUMMARY

This limited inspection of an ethnic food manufacturer currently operating under Consent Decree No. 09 C 1415 (Consent Decree) was initiated by the Chicago District Office in order to assess the firm's commitments as they related to correcting Good Manufacturing Practice (GMP) deficiencies. The firm signed the Consent Decree on 3/2/09 and the document was entered into court on 3/6/09. The inspection was conducted in accordance with Compliance Program 7303.803, Domestic Food Safety. The inspection was limited to verifying the firm's corrective actions related to facility repairs and newly implemented sanitation practices within the flour tortilla product manufacturing area.

An inspection that took place 12/4/08 – 1/8/09 and was classified [REDACTED] That inspection cited the firm for:

- Failure to store toxic chemicals safely away from food and/or food contact surfaces;
- Condensate dripping into cooking tubs;
- Failure to process and hold food in conditions that minimize contamination; and,
- Failure to operate fans in a way that minimizes contamination.

A 3/24/09 establishment inspection was initiated in response to a report that the firm shipped flour tortilla products in Interstate commerce in violation of the Consent Decree. That inspection was classified as [REDACTED] because it confirmed three commercial shipments of flour tortilla products by the

Establishment Inspection Report

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firm to food distributors, two of which were located outside of the State of Illinois. No FDA-483, Inspectional Observations, was given to the firm at the conclusion of the inspection.

The previous inspection took place 4/7-14/09 and was classified as [REDACTED] That inspection resulted in the following findings:

- The firm continued to manufacture flour tortilla products after the Consent Decree was signed on 3/2/09; however, the firm's last day of commercial-scale manufacturing was 3/5/09. The firm ceased the manufacture of flour tortilla products on 3/6/09 due to the fact that the Consent Decree was entered into court on that day.
- The firm made multiple shipments of flour tortilla products to food distributors, grocery stores and restaurants after the Consent Decree was signed on 3/2/09 and after the Consent Decree was entered into court on 3/6/09.
- The firm had posted multiple copies of the Consent Decree throughout the facility; however, the firm had not posted any copies of the Consent Decree that are translated into Spanish. The firm was reportedly in the process of translating the Consent Decree into Spanish.

This current inspection was initiated on 4/24/09 after credentials were presented and a FDA-482, Notice of Inspection, was given to Dorothy De La Torre, Manager. Ms. De La Torre was the most responsible person onsite at the time. I gave Ms. De La Torre the letter granting Del Rey Tortilla, Inc. permission to resume production of flour tortilla products. Ms. De La Torre stated that the firm was not ready to start production yet; however, they would be ready by the afternoon. I left for the District Office and returned to the firm that afternoon. I observed approximately 3.5 hours of production including loading of raw materials into the dough mixers, the handling of the raw dough, the processing and baking of the dough, and the packaging of the cooked flour tortillas. Employees were observed to be complying with the firm's newly implemented sanitation procedures. No unmarked containers were observed in, or in the vicinity of, the production area. No potentially deleterious substances, including cleaning agents and mechanical lubricants, were observed in the production area. The firm was utilizing inkjet-type printers to spray product codes onto packaging.

No FDA-483, Inspection Observations, was given to the firm at the conclusion of this inspection. No refusals were encountered and no samples were collected.

ADMINISTRATIVE DATA

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

Establishment Inspection Report

Del Rey Tortilleria, Inc.
Chicago, IL 60639

FEI: 1000115118
EI Start: 04/24/2009
EI End: 04/24/2009

Chicago, IL 60639-3007

Dates of inspection: 4/24/2009
Days in the facility: 1
Participants: Jason F. Chancey, Investigator

HISTORY

Del Rey Tortilleria, Inc. (Del Rey) is located in a [REDACTED] square foot three-story brick building. The firm has been in business for over 46 years although it was not incorporated in the State of Illinois until 6/21/78. The firm has approximately [REDACTED] fulltime employees. The firm has been located in this facility for over 20 years. This is the firm's main facility. All of the firm's flour tortillas and flour tortilla products (i.e. fried flour tortilla chips) are manufactured at this facility. The firm also manufactures various corn-based products at this facility including masa, corn tortillas, and fried corn tortilla chips. The main entrance to the facility is a retail section where the general public can purchase Del Rey products.

The firm has two other manufacturing locations at:

1023 W. 18th St.
Chicago, Illinois 60608

2701 S. Trumbull Ave.
Chicago, Illinois 60623

Corn tortillas are reportedly manufactured at these facilities and both facilities have retail sections where the general public can purchase Del Rey products. No wheat-based products are reportedly produced at these facilities.

The office operates Monday through Friday, 9:00 AM – 5:00 PM and from 8:00 AM – 1:00 PM on Saturday. Manufacturing operations are conducted Monday through Thursday, 6:00 AM – 6:00 PM. Major cleaning operations are conducted at the firm on Fridays although some cleaning is done daily. The retail store is open for business Monday through Sunday, 6:00 AM – 6:00 PM.

The firm is registered per the BioTerrorism Act.

The firm's products were associated with food-borne illnesses in the State of Massachusetts in September 2003 and May 2004 in addition to a similar event that took place in the State of Wisconsin in October 2007. The firm signed Consent Decree No. 09 C 1415 on 3/2/09 and the document was entered into court on 3/6/09. The Consent Decree specifically addresses the firm's manufacture and distribution of flour tortillas at this facility.

Establishment Inspection Report
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For a more detailed explanation of the firm's inspectional history, refer to the January 2009 EIR.

JURISDICTION

The firm has reportedly not manufactured any flour tortillas since the batch that was manufactured on 3/23/09. That batch was reportedly manufactured so that the firm could send flour tortillas to an analytical laboratory for various analyses including nutritional and chemical analysis.

The firm has continued to manufacture corn products including masa, tortillas, tostadas, and chips.

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

I presented my credentials and issued the FDA-482 to Dorothy De La Torre on 4/24/09. The FDA-482 was modified to reflect the Consent Decree. Ms. De La Torre had previously identified herself as the most responsible person for the firm except when the firm's President, Jeanette A. Toledo was present. Ms. Toledo was not present at any time during the inspection. Ms. De La Torre previously stated that she was responsible for the day-to-day operations at the firm, although no significant operational decisions could be made without approval from Ms. Toledo. Ms. De La Torre had previously demonstrated her position of authority by instructing other employees to get documents and make copies. Ms. De La Torre did was onsite throughout the inspection; however, she did not actively participate in the inspection.

Also present during the inspection were [REDACTED] and [REDACTED] both of whom were consultants hired by the firm in response to the Consent Decree and to help the firm come into compliance with GMPs. [REDACTED] was present throughout the course of the inspection. [REDACTED] was present for most of the inspection, but had to leave the facility prior to the end of the inspection. They answered questions and provided information as requested. [REDACTED] showed me a copy of the letter sent to the Chicago District Office that outlines the firm's sanitation procedures and training programs. (Exhibit 1)

Marcellina (Marcy) M. Toledo was also present for a portion of the inspection; however, she did not actively participate in the inspection.

FIRM'S TRAINING PROGRAM

[REDACTED] and [REDACTED] conducted a sanitation training program between my two visits to the facility. The sanitation training was identical to that described in the firm's 4/16/09 letter to FDA Chicago District Compliance Branch Director Richard Harrison. In fact, [REDACTED] stated that the other materials enclosed in the aforementioned 4/16/09 letter (including sanitation procedures and recipes) were identical to those being used by the firm. [REDACTED] showed me a copy of the materials to compare against my copy of the materials attached to the 4/16/09 letter. No discrepancies were noted. Training was provided in both English and Spanish. Marcy M. Toledo provided the Spanish translation of the training. The firm had all trained employees sign off as having attended and

Establishment Inspection Report

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understood the training. Ms. De La Torre stated that the few employees who were unable to make 4/24/09 training session would be trained prior to their being allowed to work. Copies of the training materials are included with this Establishment Inspection Report (EIR) as Exhibit 1, pages 27 – 66.

MANUFACTURING/DESIGN OPERATIONS

The firm's equipment and overall flour tortilla manufacturing process remains unchanged from previous inspections. Several facility repairs and improvements were pointed out by [REDACTED] and [REDACTED] including the installation of hooks outside the employee bathrooms for employees to hang work clothes while they are in the bathroom, repainted equipment, insulated overhead piping, and repaired areas of the floor (including repaired drains). No unmarked containers were observed in the production area. The door to the cleaning supplies room was demonstrated to be locked.

Several issues with the facility were noted while inspecting the facility and the equipment including:

- A floor drain cover located on the north side of the facility, near the hallway leading to the office and retail area, was observed to be displaced from the drain and it lacked holes to facilitate drainage.
- A shard of [REDACTED] was sticking out of the [REDACTED] shield over Line 2's dough baller machine.
- Condensation was observed to be forming and dripping off of several small segments of uninsulated piping including one segment directly above the scale used to weigh the shortening that is used to make the dough for flour tortilla products and a segment of piping above the pathway where dough is transported between a large mixing unit and the two tortilla lines used to manufacture 10" and larger flour tortilla products.
- Several chain links on Line 7's cooling belts were observed to be broken and/or missing segments.
- A large bolt was present on top of Line 7's oven. There was no obvious site for the bolt to fit into, suggesting that it was either an extra part that was not used or that a hole in the machine is missing the bolt.

I pointed out all of these items to [REDACTED] and/or [REDACTED]. They stated that the items would be formally addressed by the firm after the current day of production. [REDACTED] pulled that table on which the scale was located away from underneath the segment of uninsulated piping that was dripping. At the conclusion of the inspection, Ms. De La Torre stated that she instructed her maintenance personnel to immediately make all of the necessary repairs.

Also observed during the inspection of the facility was a leak in the firm's corn treatment system for making masa. A PVC pipe was observed to be leaking, resulting in periodic spouts of water being shot several feet in the air each time the system cycled. The corn treatment system is located in the warehouse area adjacent to the main loading docks.

Establishment Inspection Report

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Employees were all observed to be wearing gowns and hairnets. Employees with beards were observed to be wearing beard nets. The firm does not have a set policy for personnel with mustaches. Some employees were wearing latex gloves; however this practice was not consistent. [REDACTED] explained that because the tortilla dough is moist and sticky, employees were having difficulty keeping their gloves on and intact while handling the dough. Additionally, employees handling hot tortillas experienced difficulty due to melting gloves. The firm made a decision to permit personnel who perform these kinds of tasks to not wear gloves. Employees were not observed to be wearing untoward jewelry. No deficiencies were noted in employee sanitation practices through the course of the inspection.

The firm was manufacturing 6", 8" and #3 size flour tortillas during the inspection.

MANUFACTURING CODES

The firm was using its two inkjet printers to print lot codes on packages of flour tortilla products. Use by dates range from 30 – 45 days, depending on the season. The date coding was consistent with the example provided in Exhibit 1, page 26.

REFUSALS

No refusals were encountered through the course of this inspection.

ADDITIONAL INFORMATION

[REDACTED]

During discussion with Dr. Clark, he stated that the firm's 3/23/09 manufacturing operations where 100 lbs of flour tortillas were produced was because he wanted to see the manufacturing process and to have product sent out for nutritional and chemical analysis.

EXHIBITS COLLECTED

1. Sanitation Program and Training Materials (66 pages)

ATTACHMENTS

- FDA-482, dated 4/24/09

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