

Establishment Inspection Report

Del Rey Tortilleria, Inc.
Chicago, IL 60639-3007

FEI: 1000115118
EI Start: 03/10/2006
EI End: 03/20/2006

SUMMARY

This limited inspection was conducted per FACTS assignment number 720763, FY 06 work plan, and Compliance Program 7303.803 (Domestic Food Safety). This inspection was limited to accompanying Illinois Department of Public Health (IDPH) on a re-inspection to verify corrections to problems found on 12/16 and 12/22/2005. In addition, IDPH obtained the firm's current flour tortilla manufacturing formula.

On 3/10/06, I showed my credentials and issued an FDA-482, Notice of Inspection to Mr. Santos (NMI) Perez, Maintenance Manager. Mr. Perez was the most responsible individual available at the firm at the time of issuance. Ms. Blanca Roja, Secretary, accompanied Environmental Health Specialist Timothy Shekelton and I during the inspection. Mr. Perez had to leave the Grand Ave location for another Del Rey site. Ms. Marcellina Toledo instructed Ms. Roja to accompany us via a telephone conversation.

During this inspection, I obtained an affidavit signed by Ms. Marcellina M. Toledo, General Manager, showing the flour tortilla formulas used at Del Rey Tortilleria.

All other information is the same as previous reports.

Photographs were taken.

No samples were collected.

No refusals were encountered.

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: 3/10/2006, 3/15/2006, 3/20/2006

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Days in the facility: 3
Participants: Nicole J. Clausen, Investigator

INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED

The individual responsibility shown below has not changed since the last inspection.

Jeanette A. Toledo, President/Owner – Ms. J. Toledo is the sole owner of all Del Rey Tortilleria, Inc facilities. She is the most responsible individual at Del Rey Tortilleria. Ms. J. Toledo makes all executive decisions and controls the firm's finances. Ms. J. Toledo also approved the decision to recall Del Rey products and authorizes money for any improvement or changes. She is unable to be present at the firm on a frequent basis due to illness but Ms. M. Toledo discusses all business decisions with Ms. J. Toledo prior implementing changes. She has the power and authority to make tortilla formula changes.

Mr. Refugio (NMI) Martinez, Vice President – Mr. Martinez reports to Ms. J. Toledo. He does not have any defined responsibilities and does whatever Ms. J. Toledo tells him to do. Mr. Martinez is present at the firm a couple days a week. Mr. Martinez is married to Ms. J. Toledo.

Ms. Marcellina (Marcy) M. Toledo, General Manager - Ms. M. Toledo is the most responsible individual present at Del Rey Tortilleria on a daily basis. She is responsible for and has knowledge of daily manufacturing and office operations, safety, quality, product development, receiving raw materials, and facility inspections. Ms. M. Toledo also has hiring and firing authority and signs company checks. In addition, she oversees the other two Del Rey facilities. Ms. M. Toledo reports to, runs decisions past, and follows Ms. J. Toledo's directions. Ms. M. Toledo stated that everyone follows instructions from Ms. J. Toledo. Ms. M. Toledo explained to me (NJC) that when the recall decision was made she had consulted Ms. J. Toledo prior to discussing it with their lawyer. Ms. M. Toledo will recommend changes, improvements, and repairs to Ms. J. Toledo and Ms. J. Toledo authorizes the implementation of these changes. Ms. M. Toledo is the granddaughter of Ms. J. Toledo but Ms. M. Toledo also refers to her as her mother.

MANUFACTURING/DESIGN OPERATIONS

This inspection confirmed that Del Rey Tortilleria is manufacturing flour tortillas with the following formula:

████████ flour

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██████ vegetable shortening
██████ baking powder
██████ calcium propionate
██████ salt
██████ (metabisulfite)
██████
██████ water (approximately ██████)

The above formula was implemented on February 8, 2006 (Exhibit 1). All information regarding the change in the flour tortilla formulas was captured in attached affidavit signed by Ms. Marcellina M. Toledo, General Manager. All mixing and raw ingredient products that are weighed out have the mix formula on the container (Exhibit 2). Photographs of the tortilla manufacturing operations were also taken (Exhibit 3).

A copy of IDPH's Sanitary Inspection Report is also attached (Exhibit 4).

OBJECTIONABLE CONDITIONS AND MANAGEMENT'S RESPONSE

This was a limited inspection; no FDA-483 was issued.

ATTACHMENTS

FDA-482, Notice of Inspection dated 3/10/2006
Affidavit signed by Ms. Marcellina M. Toledo

EXHIBITS COLLECTED

- Exhibit 1 – Flour tortilla formula change of calcium propionate to ██████ signed by production managers
- Exhibit 2 – Photograph of partial formula on mixing and ingredient buckets
- Exhibit 3 – Photographs of tortilla manufacturing operations
- Exhibit 4 – IDPH Sanitary Inspection Report
- Exhibit 5 – FDA-525 containing photographs

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Nicole J. Clausen, Investigator