



## FDA News

**FOR IMMEDIATE RELEASE**

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### **FDA Shuts Down a Flour Tortilla Manufacturer for Repeated Violations** *Failure to correct drove action*

The U.S. Food and Drug Administration (FDA) today announced that Del Rey Tortilleria Inc., Chicago, Ill., its president, and two general managers have entered into a consent decree of permanent injunction that prevents Del Rey Tortilleria from manufacturing and distributing soft-shell flour tortillas until the company obtains FDA approval.

FDA's enforcement action follows the company's extensive history of violating the Agency's current Good Manufacturing Practice (cGMP) requirements for food. The complaint, filed by the United States Attorney in Chicago, alleges that Del Rey Tortilleria's manufacturing operations do not adequately protect consumers against the risk of contamination.

"We cannot allow a company to produce potentially contaminated products because of failing to have adequate procedures in place," said Michael Chappell, acting associate commissioner for regulatory affairs at FDA. "This enforcement action shows the FDA will take the appropriate measures deemed necessary under the Federal Food, Drug and Cosmetic Act to protect the public's health."

During FDA inspections, the agency found several violations including cleaning chemicals stored improperly, unsuitable containers used for food processing, and other unsanitary conditions inside the Illinois plant. According to the complaint, flour tortillas manufactured by Del Rey Tortilleria were associated with several outbreaks of gastrointestinal illness in school children, resulting in a product recall by the company.

Del Rey Tortilleria must hire sanitation and food processing experts to develop quality control measures and to inspect and certify that the company complies with cGMP and meets other consent decree requirements. The defendants may resume manufacturing and distributing soft-shell flour tortillas only after the FDA inspects the facility and determines that the defendants are in compliance with the decree, cGMP, and the Federal

Food, Drug & Cosmetic Act.

Failure to comply with the consent decree could result in the FDA ordering the defendants to stop manufacturing and distributing food, to recall products or to take other corrective actions. In addition, the defendants could be ordered to pay \$6,000 per day for being non-compliant.

Should consumers have any food safety questions, they can call the FDA's toll-free Food Safety Hotline at (888) SAFEFOOD, and they can report any problems to the FDA consumer complaint coordinator in their geographic area. Contact numbers may be found online at [www.fda.gov/opacom/backgrounders/complain.html](http://www.fda.gov/opacom/backgrounders/complain.html).