UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

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| UNITED STATES OF AMERICA, | ) | FILED: MARCH 6, 2009 |
| | ) | 09CV1415 |
| Plaintiff, | ) | JUDGE HART |
| | ) | MAGISTRATE JUDGE COX |
| v. | ) | AO |
| | ) | |
| DEL REY TORTILLERIA, INC., an Illinois corporation, JEANETTE A. TOLEDO, MARCELLINA M. TOLEDO, and DOROTHY L. DE LA TORRE, individuals, | ) | |
| | ) | |
| Defendants. | ) | |

**COMPLAINT**

The United States of America, by its attorney, Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois, for its complaint against the above-named defendants, states as follows:

**Introduction**

1. This proceeding is brought on behalf of the United States Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 332(a), to enjoin Del Rey Tortilleria, Inc. ("Del Rey"), a corporation, and Jeanette A. Toledo, Marcellina M. Toledo, and Dorothy L. De La Torre, individuals (collectively "defendants" or "Del Rey"), from violating 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) and from violating 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce.

**Jurisdiction and Venue**

2. This Court has jurisdiction over this action pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345, and personal jurisdiction over all parties. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

**The Defendants**

3. The defendant, Del Rey, is incorporated under the laws of the State of Illinois and is doing business at 5201 West Grand Avenue, Chicago, Illinois, within the jurisdiction of this Court. Del Rey is doing business at two other locations in Chicago – 1023 West 18th Street and 2701 South Trumbull – within the jurisdiction of this Court.

4. The defendant, Jeanette A. Toledo, is the president and sole owner of Del Rey. She has final authority over manufacturing operations and financial decisions at Del Rey and was responsible for authorizing recalls of Del Rey's tortilla products. She conducts her business at 5201 West Grand Avenue, Chicago, Illinois, within the jurisdiction of this Court.

5. The defendant, Marcellina M. Toledo, one of the general managers at Del Rey, is responsible for the day-to-day operations including product safety and quality, product development, and raw material receipt. She is also responsible for hiring and firing employees. She conducts her business at 5201 West Grand Avenue and 1023 West 18th Street, Chicago, Illinois, within the jurisdiction of this Court.

6. The defendant, Dorothy L. De La Torre, one of the general managers at Del Rey, is responsible for the day-to-day operations including product safety and quality, product development, and raw material receipt. She is also responsible for hiring and firing employees. She conducts her business at 5201 West Grand Avenue, Chicago, Illinois, within the jurisdiction of this Court.

7. The defendants manufacture flour tortillas, fried tortilla chips, tostadas, and masa (corn flour). They sell their products retail and wholesale to a variety of establishment types including restaurants, fast food chains, grocery stores, food processors, and distributors. The defendants' flour tortillas are distributed in interstate commerce. The raw ingredient premix that the defendants use to manufacture their flour tortillas is also shipped in interstate commerce.

8. The defendants adulterate their articles of food by manufacturing them in a manner that fails to conform to current good manufacturing practice (CGMP) requirements, set forth at 21 C.F.R. Part 110, which causes the articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or may have been rendered injurious to health.

9. Soft-shell flour tortillas manufactured by the defendants have been associated with outbreaks of sudden gastrointestinal illness in school children.

**The Defendants' CGMP Violations**

10. CGMP requires, among other things, that:

a. toxic chemicals used or stored in a plant where food is manufactured are limited to those needed to keep the plant clean, sanitary, and operational; cleaning chemicals are stored properly; equipment and utensils are cleaned and sanitized in a manner that protects against contamination of food, food-contact surfaces, and food-packaging materials; and the plant is maintained in a sanitary, pest-free condition, 21 C.F.R. § 110.35;

b. all aspects of food manufacturing are conducted in accordance with adequate sanitation principles and appropriate quality controls to ensure that food is suitable for human consumption, and all reasonable precautions are taken to ensure that production procedures

do not contaminate food with chemicals, toxins, microorganisms, or filth, 21 C.F.R. § 110.80;

c. all reasonable measures and precautions are taken to avoid contamination of food by personnel as a result of illness or unhygienic practices, 21 C.F.R. § 110.10;

d. the plant is equipped with adequate sanitary controls for its water supply, plumbing system, and sewage and garbage disposal, 21 C.F.R. § 110.37;

e. the plant is designed to facilitate maintenance and sanitary operations for food manufacturing, 21 C.F.R. § 110.20; and

f. all equipment and utensils are designed, constructed, and maintained in an appropriate sanitary condition, 21 C.F.R. § 110.40.

11. FDA conducted six inspections of the defendants' plant located at 5201 West Grand Avenue between 2003 and 2009. The 2009 inspection took place on December 4 and 18, 2008, and January 8, 2009. The dates of the 2008 inspection were November 8-9, 15-16, 20, 27-29, 2007, December 18, 2007, January 28-29, 2008, and February 7, 2008. The 2006 inspection took place on December 16, 19-21, 2005, and January 11, 2006. Three previous inspections were conducted in September 2004 (on August 16, 20, 27, and September 3, 2004), in May 2004 (on May 17-18, 20-22, and 25, 2004), and in 2003 (on October 16-18, 20, 24, 29 and November 7, 2003).

12. FDA's inspections establish that the defendants do not comply with CGMP requirements and that they manufacture articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) because the food has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. The defendants fail to have adequate control over their manufacturing process, toxic

chemical storage, sanitizing and cleaning operations, employee health and hygiene, pest access, installation or maintenance of sanitation systems, and the construction or maintenance of equipment and utensils in their plant. The defendants do not conduct their operations in a manner that protects against contamination of food.

13. The FDA investigators observed that:

a. cleaning and other toxic chemicals were stored near raw ingredients and in food processing areas (see 21 C.F.R. §§ 110.35(b) and 110.80(b)(2)), for example,

i. an alkaline cleaner was stored in the tortilla production area and a cleaner and degreaser was stored in the tostada cooking room,

ii. a WD-40 can and dish soap were stored near containers of raw ingredients,

iii. a WD-40 can was stored on the tortilla chip packaging machine, a soda bottle containing a blue cleaning liquid was stored on a shelf of a weigh table for preparing raw ingredients, and a 5-gallon spray container of pesticide was stored in an office closet in the tortilla production area,

iv. an uncovered bucket containing epoxy residue and water was stored near uncovered in-process raw ingredients and a mixer in the tortilla processing area, and

v. two 55-gallon drums of hydraulic oil were stored near in-process materials in the flour tortilla processing area,

during the 2009, 2006, 2004, 2003, and the 2003 and May 2004 inspections, respectively;

b. unsuitable containers were being used for holding raw materials and for food processing (see 21 C.F.R. § 110.80(a)(5), (b)(2)), for example,

i. a detergent bucket was used as a corn strainer,

ii. a bucket with a chemical label was used to hold raw ingredients for flour tortillas, a bucket with a disinfectant cleanser label was used for dissolving a raw ingredient for manufacturing flour tortillas, and a paint bucket was used to hold in-process raw materials, and

iii. paint buckets were used to hold raw ingredients and a bucket with a chemical label was used to mix raw ingredients for manufacturing flour tortillas,

during the 2009, 2006, and 2004 inspections, respectively;

c. raw materials were being stored in a manner that does not protect against contamination of food (see 21 C.F.R. § 110.80(a)(1)), for example, raw ingredients or in-process materials were held in unlabeled buckets in the flour tortilla processing area during the 2008, 2004, and 2003 inspections;

d. employees were using unhygienic practices (see 21 C.F.R. § 110.10(a)) during the 2008, 2006, and May 2004 inspections;

e. plumbing systems and other physical facilities of the plant were inadequately installed or maintained (see 21 C.F.R. §§ 110.20(b)(4), 110.37(b)), for example,

i. there was a condensate-like liquid over the cooking tubs holding in–process and cooked corn flour,

ii. a hot water pipe was dripping water onto a bag of flour on the raw ingredient staging platform,

iii. there was a sewage backup in the food warehouse and a lack of protection from water backflow for a sink and spray pipe in the corn tortilla processing area, and

iv. there was condensate spraying from air vent and dripping on a cooling rack carrying flour tortillas and a lack of backflow protection from a water pipe located in the garage area,

during the 2009, 2006, 2004, and 2003 inspections, respectively;

f. ineffective measuring were being taken to exclude pests from the plant, including food processing and storage areas (see 21 C.F.R. § 110.35(c)), during the 2008 and 2004 inspections; and

g. other conditions and practices that do not protect against contamination of food were on-going, for example, built-up grease and dirt were on the cooling fans operating directly over product lines (see 21 C.F.R. § 110.20(b)(6)) in each inspection.

14. Because the defendants' food is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health, it is adulterated within the meaning of 21 U.S.C. § 342(a)(4).

15. By introducing, or delivering for introduction, into interstate commerce food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), the defendants violate 21 U.S.C. § 331(a).

16. By causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce, the defendants violate 21 U.S.C. § 331(k).

**Outbreaks of Gastrointestinal Illness Associated with the Defendants' Flour Tortillas**

17. There have been several outbreaks of gastrointestinal illness in school children following consumption of meals such as chicken fajitas and tacos prepared with Del Rey's flour tortillas. Symptom onset was usually within one hour of eating. The predominant symptoms were nausea, headache, abdominal cramps, vomiting, and dizziness. An outbreak of gastrointestinal illness linked to Del Rey's flour tortillas occurred in October 2007 in Wisconsin. Previous outbreaks of gastrointestinal illnesses associated with Del Rey's flour tortillas occurred in Massachusetts in May 2004 and September 2003.

**Prior Warning**

18. The defendants are well aware that their practices violate the Act and FDA regulations. FDA has warned the defendants repeatedly that their conduct violates the law. FDA has inspected the defendants' operations six times between 2003 and 2009. At the close of each inspection, the investigators presented the Lists of Inspectional Observations (Forms FDA-483) and discussed the documented deviations with Ms. Dorothy L. De La Torre in 2009 and, in the previous inspections, Ms. Marcellina M. Toledo or, in one instance, her agent.

19. The defendants have failed to take the necessary steps to prevent recurrence of CGMP violations. For example, despite the defendants' promised corrections in letters dated June 18, 2004, and September 24, 2004, to FDA, the FDA investigators observed many of the same or similar objectionable conditions and practices at subsequent inspections, including the most recent inspection in 2009. Even when the defendants made corrections while the FDA investigators were

at the plant conducting an inspection, most of the corrections were notably absent upon the FDA investigators's return to conduct the next inspection.

**Request for Relief**

20. Because FDA's inspections have been insufficient to obtain the defendants' voluntary compliance with the Act and FDA regulations, FDA believes that injunctive relief is necessary to restrain Del Rey and the individual defendants from continuing to manufacture and distribute adulterated food.

WHEREFORE, the plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin the defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of the Court's order:

A. From violating 21 U.S.C. § 331(a) by introducing, or delivering for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); and

B. From violating 21 U.S.C. § 331(k) by causing articles of food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) while such articles are held for sale after shipment of one or more ingredients in interstate commerce; and

II. Order the defendants and each and all of their officers, agents, employees, successors, assigns, and attorneys, and any persons in active concert or participation with any of them who receive notice of the Court's order, to cease manufacturing, preparing, packing, labeling, and distributing at their plant located at 5201 West Grand Avenue, Chicago, Illinois, any soft-shell flour

tortilla and until the defendants bring their plant and operations into compliance with the Act and FDA regulations to the satisfaction of FDA; and

III. Award the plaintiff its costs incurred in pursuing this action and such other relief as the Court may deem just and proper.

Dated: March 6, 2009.

Respectfully submitted,

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United States Attorney

By: s/ Donald R. Lorenzen

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