UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 09 C 1415
	)	
DEL REY TORTILLERIA, INC., an Illinois corporation, JEANETTE A. TOLEDO, MARCELLINA M. TOLEDO, and DOROTHY L. DE LA TORRE, individuals,	)	Judge Hart
	)	
Defendants.	)	

CONSENT DECREE

The United States of America, by its attorney, Patrick J. Fitzgerald, United States Attorney for the Northern District of Illinois, having filed a complaint for permanent injunctive relief against Del Rey Tortilleria, Inc., a corporation, and Jeanette A. Toledo, Marcellina M. Toledo, and Dorothy L. De La Torre, individuals (collectively "defendants" or "Del Rey"), and the defendants having appeared and consented to entry of this decree without contest and before any testimony has been taken, and the United States having consented to this decree, it is hereby

ORDERED, ADJUDGED, AND DECREED that:

1. This court has jurisdiction over the subject matter and over all parties to this action.

2. The complaint for injunction states a claim for relief against the defendants under the Federal Food, Drug, and Cosmetic Act ("Act"), 21 U.S.C. § 301 *et seq*.

3. The defendants violate the Act, 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).

4. The defendants violate the Act, 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.

5. Upon entry of this decree, 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 this decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly receiving, manufacturing, preparing, packing, labeling, and distributing at their plant located at 5201 West Grand Avenue, Chicago, Illinois (and any other or new location at which the defendants receive, manufacture, prepare, pack, label, hold, or distribute articles of food), any soft-shell flour tortilla unless and until the following occur:

a. The defendants select an expert or experts (the "Sanitation Expert") having no personal or financial ties (other than a consulting agreement) to the defendants or the defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a written sanitation control program, covering the defendants' manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and plant construction and maintenance (including the plant's buildings and sanitation-related systems (plumbing, sewage disposal), equipment, and utensils contained therein), to protect against contamination of food, food-contact surfaces, and food-packaging materials with chemicals, toxins, microorganisms, and filth, and:

i. The defendants inform the United States Food and Drug Administration (FDA) in writing of the name and qualifications of the Sanitation Expert(s) as soon as they retain such expert;

ii. The Sanitation Expert(s) develops a written sanitation control program for preparing, packing, holding, and distributing the defendants' articles of food, as described in subparagraph 5a.;

iii. FDA approves, in writing, the sanitation control program developed by the Sanitation Expert(s);

iv. The defendants make English and Spanish versions of the sanitation control program available and accessible to all their employees;

v. The defendants develop a written employee training program (in English and Spanish) that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and the defendants document that each employee has received such training;

vi. The defendants assign the responsibility and authority for implementing and monitoring the sanitation control program on a continuing basis to an employee who is trained in sanitation control requirements;

vii. The Sanitation Expert(s) inspects the defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether the defendants have adequately established and implemented the FDA-approved sanitation control program, whether the defendants have adequately addressed the FDA investigators'

inspectional observations listed on each Form FDA-483 issued to the defendants since November 2003, and whether the defendants comply with Current Good Manufacturing Practice (CGMP) requirements set forth in 21 C.F.R. Part 110; and

viii. The Sanitation Expert certifies, in writing, to FDA that the defendants:

(1) have adequately established and implemented the FDA-approved sanitation control program;

(2) have adequately addressed the Form FDA-483 observations; and

(3) comply with the CGMP requirements in 21 C.F.R. Part 110.

b. The defendants select an expert (the "Food Processing Expert") having no personal or financial ties (other than a consulting agreement) to the defendants or the defendants' manufacturing operations and who, by reason of background, education, training, and experience, is qualified to develop, and ensure adequate implementation of, a food processing quality control program, covering the defendants' processes for preparing, packing, and holding soft-shell flour tortillas, to prevent ingredient mix-ups and ensure that the soft-shell flour tortillas manufactured by the defendants consistently contain the type and amount of ingredients that they are intended to contain, based on pre-established written batch formulations, and:

i. The defendants inform FDA in writing of the name and qualifications of the Food Processing Expert as soon as they retain such expert;

ii. The Food Processing Expert develops a food processing quality control program, as described in subparagraph 5b, and such food processing quality control program, at a minimum, requires:

(1) applying and maintaining identification of raw ingredients in English and Spanish on raw ingredient containers;

(2) using appropriate proportions of raw ingredients in the soft-shell flour tortillas manufactured by the defendants;

(3) for each size of soft-shell flour tortillas manufactured by the defendants, establishing written batch formulations, which include the name and amount of the raw ingredients and the complete manufacturing instructions;

(4) for each batch of soft-shell flour tortillas manufactured by the defendants, preparing a batch production record, which documents that each step in the established written batch formulation for the product was followed, and lists the lot numbers of each raw ingredient used in the batch production; and

(5) for each retail and bulk package of soft-shell flour tortillas manufactured by the defendants, placing an indelible manufacturing date and time code in a conspicuous location on the back panel of the package where it is easily readable;

iii. FDA approves, in writing, the food processing quality control program developed by the Food Processing Expert;

iv. The defendants make English and Spanish versions of the food processing quality control program – including the established written batch formulation for each size of soft-shell flour tortillas manufactured by the defendants – available and accessible to all their employees;

v. The defendants develop a written employee training program (in English and Spanish) that includes, in addition to the requirements in subparagraph 5a, instruction in proper food processing techniques and food processing quality control, and the defendants document that each employee has received such training;

vi. The defendants assign the responsibility and authority for implementing and monitoring the food processing quality control program on a continuing basis to an employee who is trained in food processing quality control requirements;

vii. The Food Processing Expert inspects the defendants' plant, equipment, utensils, articles of food, and relevant records contained therein, to determine whether the defendants have adequately established and implemented the FDA-approved food processing quality control program; and

viii. The Food Processing Expert certifies, in writing, to FDA that the defendants have adequately established and implemented the FDA-approved food processing quality control program;

c. The defendants, under FDA supervision, examine raw ingredients and in-process and finished articles of foods at the defendants' plant, and the conditions under which they have been stored or held, and the defendants destroy, under FDA supervision, all raw ingredients and in-process and finished articles of food as and when FDA deems necessary;

d. FDA, as it deems necessary to evaluate the defendants' compliance with the terms of paragraph 5, conducts inspections of the defendants' plant, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

e. The defendants pay the costs of any supervision, inspection, analyses, examination, and review that FDA deems necessary to evaluate the defendants' compliance with the terms of paragraph 5; and

f. FDA notifies the defendants in writing that the defendants appear to be in compliance with the requirements set forth in subparagraphs 5a through 5e, 21 C.F.R. Part 110, and the Act.

6. Upon resuming operations after completing the requirements of paragraph 5, the defendants shall notify FDA in writing of any change in the type or amount of raw ingredients in any batch formulation for soft-shell flour tortillas (including, but not limited to, switching from an ingredient pre-mix to individually packaged ingredients) or any change in manufacturing instructions for any soft-shell flour tortilla, at least ten (10) calendar days before implementing any such change.

7. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the defendants' plant located at 5201 West Grand Avenue, Chicago, Illinois, and any other or new locations at which the defendants receive, manufacture, prepare, pack, label, hold, or distribute articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this decree, 21 C.F.R. Part 110, and the Act. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of the defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, manufacturing, preparing, packing, labeling, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this decree and appropriate credentials. The inspection authority granted by this decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. The defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate the defendants' compliance with this decree, at the standard rates prevailing at the time the costs are incurred. As of the date that this decree is signed by the parties, these rates are: $85.49 per hour and fraction thereof per representative for inspection work; $102.49 per hour or fraction thereof per representative for analytical or review work; $0.55 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for

subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the court.

9. 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 this decree, are permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from directly or indirectly doing or causing any act that:

a. violates the Act, 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);

b. violates the Act, 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; or

c. failing to implement and continuously maintain the requirements of this decree.

10. If, at any time after entry of this decree, FDA determines, based on the results of an inspection, sample analysis, or other information, that the defendants have failed to comply with any provision of this decree, have violated 21 C.F.R. Part 110 or the Act, or that additional corrective actions are necessary to achieve compliance with this decree, 21 C.F.R. Part 110 or the Act, FDA may, as and when it deems necessary, issue a directive notifying the defendants in writing of the noncompliance and ordering the defendants to take appropriate action, including but not limited to ordering the defendants immediately to take one or more of the following actions:

a. cease receiving, manufacturing, preparing, packing, labeling, holding, or distributing articles of food until the defendants receive written notification from FDA that the defendants appear to be in compliance with the decree, 21 C.F.R. Part 110, and the Act, and that the defendants may resume operations;

b. recall all articles of food that have been distributed or are under the custody and control of the defendants' agents, customers, or consumers;

c. submit samples of articles of food to a qualified laboratory to determine whether the food contains the type and amount of ingredients that its is intended to contain and whether it is contaminated with chemicals, toxins, microorganisms, or filth;

d. take any other corrective actions as FDA deems necessary to protect the public health or bring the defendants into compliance with this decree, 21 C.F.R. Part 110, and the Act, including but not limited to requiring that the defendants re-implement or re-institute any of the requirements of this decree.

11. The provisions of paragraph 10 shall be apart from, and in addition to, all other remedies available to FDA. The defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews to implement and monitor recalls and other corrective actions, at the rates specified in paragraph 8 of this decree.

12. Upon receipt of an FDA directive described in paragraph 10, the defendants shall immediately and fully comply with the terms of the directive. In the event that the defendants disagree with the terms of the directive, the defendants may appeal to this court and shall continue

to immediately and fully comply with the terms of the directive unless and until the court modifies or overturns the directive.

13. If any defendant fails to comply with the provisions of this decree, then the defendants shall pay to the United States liquidated damages in the sum of six thousand dollars ($6,000.00) for each day that the defendant fails to comply with this decree. The defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

14. If any defendant violates this decree and is found in civil or criminal contempt thereof, the defendants shall, in addition to other remedies, reimburse the plaintiff for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

15. All decisions specified in this decree shall be vested in the sole discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the court under the arbitrary-and-capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by a court of any FDA decision rendered pursuant to this decree shall be conducted without any discovery by either party and shall be based exclusively upon the written record that was before FDA at the time the decision was made.

16. The defendants shall provide notice of this decree in the following manner.

a. Within ten (10) calendar days after entry of this decree, the defendants shall:

i. provide a copy of this decree, personally or, when necessary, by certified mail, return receipt requested, to each of their officers, agents, employees (who shall receive a copy of the decree in English and Spanish), successors, assigns, and attorneys, and any persons in active concert or participation with any of them;

ii. post a copy of this decree in English and Spanish on a bulletin board in the employee common area at the defendants' plant, and shall ensure that the decree remains posted so long as the decree remains in effect; and

iii. hold a general meeting or series of smaller meetings for their employees, at which they shall describe the terms and obligations of this decree.

b. Within twenty (20) calendar days after entry of this decree, the defendants shall provide FDA with an affidavit signed by the defendants attesting to their compliance with subparagraph 16a, stating the fact and manner of compliance, and identifying the names and positions of all persons who were notified under the requirements in subparagraph 16a.

c. Within ten (10) calendar days from the date of employment of each new employee hired by the defendants after the defendants have complied with the provisions in subparagraph 16a, the defendants shall provide the new employee with a copy of the decree (in English or Spanish, in accordance with the language spoken), personally or, when necessary, by certified mail, return receipt requested.

17. The defendants shall notify FDA in writing at least thirty (30) calendar days before any change ownership, name, or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this

decree. The defendants shall provide any prospective successor or assign with a copy of this decree at least thirty (30) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days of providing a copy of this decree to a prospective successor or assign.

18. The defendants shall address all communications with FDA required under this decree to Director, Chicago District Office, Food and Drug Administration, 550 West Jackson Boulevard, Suite 1500 South, Chicago, Illinois 60661, with a copy to the United States Attorney's Office, attention Donald R. Lorenzen, Assistant U.S. Attorney, 219 South Dearborn Street, Chicago, Illinois 60604, and shall reference this civil action by case name and civil action number in such communications.

19. Except as provided in the foregoing provisions of this decree, the parties shall bear their own costs and attorneys' fees in this action.

20. This court retains jurisdiction of this action for the purpose of enforcing or modifying this decree and for the purpose of granting such additional relief as may be necessary or appropriate.

E N T E R:

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_____
District Judge

This ____ day of _____, 2009

We hereby consent to the entry of this decree.

For Defendants:

_____
JEANETTE A. TOLEDO
on behalf of Del Rey Tortilleria, Inc.

_____
JEANETTE A. TOLEDO
in her individual capacity

_____
MARCELLINA M. TOLEDO
in her individual capacity

_____
DOROTHY L. DE LA TORRE
in her individual capacity

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Attorney for Del Rey Tortilleria, Inc.,
Jeanette A. Toledo, Marcellina M. Toledo,
and Dorothy L. De La Torre

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