

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

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UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	CIVIL ACTION NO. _____
)	
v.)	
)	<u>COMPLAINT FOR</u>
KWONG TUNG FOODS, INC.)	<u>PERMANENT INJUNCTION</u>
a corporation, and)	
VIETA “VICTOR” C. WANG and)	
JUNEY H. WANG, individuals,)	
)	
Defendants.)	
)	
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The United States of America, Plaintiff, by and through its undersigned counsel, alleges as follows:

INTRODUCTION

1. The United States of America brings this action on behalf of the United States Food and Drug Administration (“FDA”) pursuant to the Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, to permanently enjoin and restrain Kwong Tung Foods, Inc. (“Kwong Tung Foods” or “the firm”), a corporation, and Vieta “Victor” C. Wang, and Juney H. Wang, individuals (collectively, “Defendants”), from violating the Act, 21 U.S.C. § 331(k), by causing the adulteration of articles of food within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction under 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and 1391(c).

DEFENDANTS

4. Defendant Kwong Tung Foods is a Minnesota corporation that received, processed, manufactured, prepared, packed, held, and/or distributed food, namely rice and wheat noodles and mung bean and soy bean sprouts. Kwong Tung Foods is located at 1840 East 38th Street, Minneapolis, Minnesota 55407 (the “facility”), within the jurisdiction of this Court.

5. Defendant Vieta “Victor” C. Wang is the owner and President of Kwong Tung Foods. He is knowledgeable about all aspects of his company, including ordering and storage, production, sanitation, maintenance, sales and delivery, and all records associated with these activities. He has the authority to prevent, detect, and correct problems with the company’s business practices. He performed his duties at the facility, within the jurisdiction of this Court.

6. Defendant Juney H. Wang is Vice President of Kwong Tung Foods, and Defendant Victor Wang’s wife. She was responsible for quality assurance and oversaw the day-to-day production at the facility. She also supervised and trained employees. She performed her duties at the facility, within the jurisdiction of this Court.

PUBLIC HEALTH RISKS

7. Foodborne illness can be caused by consuming food that is contaminated with filth and/or bacterial pathogens.

8. A facility with poor sanitation significantly increases the risk that filth or bacterial

pathogens will contaminate the food it manufactures, resulting in a variety of risks to the public ranging from relatively mild discomfort to serious, life-threatening illness. Inadequate equipment cleaning and sanitizing may also result in filth and pathogens becoming established on equipment and contaminating the food processed using that equipment. Filth and pathogens can be transmitted from the environment and raw materials onto foods as a result of dead or living pests.

9. Allergen cross-contact contamination can occur when an allergen-containing food is inadvertently introduced to a non-allergen food, which may result in severe or even potentially life threatening reactions to sensitive or allergic individuals. This type of cross-contact contamination generally results from environmental exposure during food processing or handling, particularly when multiple foods are produced in the same facility without proper cleaning and sanitation controls. For example, wheat noodles contain major allergens such as wheat, egg, and soy, whereas rice noodles do not contain such allergens.

DEFENDANTS' VIOLATIONS

10. Rice and wheat noodles and mung bean and soy bean sprouts are food within the meaning of 21 U.S.C. § 321(f).

11. Defendants violated 21 U.S.C. § 331(k) by causing food held for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of the Act, 21 U.S.C. § 342(a)(4).

12. Defendants purchased and received ingredients (e.g., tapioca starch, potassium sorbate, salt) used to manufacture Defendants' rice and wheat noodles from a supplier who purchased the ingredients from Iowa and Kansas.

13. Defendants purchased and received seeds used for sprouting from suppliers in Kentucky and North Dakota.

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

FDA INSPECTIONS

15. FDA inspections of Defendants' facility have established that Defendants have an extensive history of operating under insanitary conditions, in violation of the Act. Both Defendant Victor Wang and Defendant Juney Wang have been present for multiple FDA inspections and personally received inspection reports and requests for corrective actions.

The 2015 Inspection

16. FDA's most recent inspection of Defendants' facility was conducted from October 14 to October 26, 2015 ("the October 2015 Inspection"), as a follow-up to a Warning Letter issued by FDA on April 9, 2015.

17. During the October 2015 Inspection, FDA investigators observed insanitary conditions, many of which were repeat observations from FDA's previous inspections of the facility. These observations included, but were not limited to, the following:

A. Failure to take effective measures to exclude pests and rodents from the facility to protect against food contamination by allowing numerous rodent excreta pellets to accumulate in both noodle and sprout production rooms and facility hallways; live and dead insects and mice to exist in the wheat noodle production room; insect webbing to form on noodle production equipment; rodent gnaw holes in a bag of mung bean seeds; and unused and/or empty

ingredient bags to be stored near production rooms, which can serve as a breeding place for pests;

B. Failure to maintain equipment and utensils in an acceptable condition through adequate cleaning and sanitization by leaving wheat noodle residue and rice noodle residue on the same cutting equipment; black mold-like substance on various pieces of equipment used for noodle production as well as those used for sprout production; heavy old product build-up and grease/debris remaining on food manufacturing equipment; and old product residue encrusted on food contact surfaces;

C. Failure to ensure adequate employee sanitation practices that may cause cross-contamination of finished product and food-contact surfaces by permitting employees leaving noodle packing stations to handle shipping boxes and to return to packing stations without washing their hands; employees to pack mung bean sprouts with their bare hands; and missing hand soap and hand sanitizer at the employee hand washing stations;

D. Failure to maintain the facility in repair by leaving damaged ceilings in two rooms in the facility and holes cut into walls in the sprout room that can harbor pests;

E. Failure to adequately package and store finished product to minimize the potential for contamination by letting condensate drip onto finished mung bean sprouts; and

F. Failure to adequately label or prevent cross-contact with major allergens by producing foods which do not contain any major allergens on equipment with visible residue of products that do include major allergens such as wheat, egg, and soy.

18. At the close of the inspection, FDA investigators issued a Form FDA 483, List of Inspectional Observations (“Form FDA 483”), to Defendant Victor Wang.

19. Defendants did not respond to this Form FDA 483, despite promises to do so.

Previous FDA Inspections

20. FDA inspected Defendants' facility at least eight times prior to the October 2015 inspection: August 28-29, 2006; June 9-11, 2009; June 15-16, 2010; December 27, 2010-January 3, 2011; January 17-25, 2012; December 13-21, 2012; May 15-16, 2014; and November 17-December 18, 2014.

21. FDA investigators observed similar unacceptable sanitation practices during these prior inspections including, but not limited to, the following:

A. Failure to exclude pests from the facility. During the 2006, 2011, 2012, and 2014 inspections, investigators found evidence of rodent and/or insect activity in various locations throughout the facility.

B. Failure to use appropriate food processing equipment and adequately clean equipment and utensils. In 2010, 2011, 2012, and 2014, mold-like substances and/or old product build-up were observed on processing equipment and utensils. Also, during the 2006, 2011, 2012, and 2014 inspections, various pieces of equipment were identified that, by design, do not accommodate adequate cleaning;

C. Failure to ensure adequate employee sanitation practices. During the 2010, 2011, 2012, and 2014 inspections, Defendants had insufficient hand-washing facilities and/or Defendants' employees failed to appropriately sanitize their hands;

D. Failure to use appropriate sanitizing agents. During the 2011 inspection, Defendants' employees poured an antimicrobial water additive for pathogen reduction on top of sprouted seeds without verifying the amount and inconsistent with its label directions;

E. Failure to properly maintain facility in repair. In 2010, pipes in a production room were observed draining directly on the floor. During the 2011, 2012, and 2014 inspections, condensation was observed dripping into food preparation areas and/or a food production room; and

F. Failure to adequately package and store finished product. During a 2014 inspection, condensate was observed dripping onto uncovered, finished sprouts in the walk-in cooler, and employees were observed packaging noodles in a manner which creates a condition favorable for microorganism growth.

22. FDA issued Forms FDA 483 at the conclusion of inspections in 2009, 2010, 2011, 2012, and 2014, and during each inspection the investigators discussed the concerns with Defendants Victor Wang and/or Juney Wang.

23. Defendants failed to adequately respond in writing to the observations noted in any of the Forms FDA 483 issued since 2009.

NOTICE OF VIOLATIONS

24. FDA gave Defendants ample notice that the firm was producing food under insanitary conditions. In addition to issuing Forms FDA 483 and discussing the observations with Defendants, FDA issued a Warning Letter to Defendant Victor Wang on April 9, 2015, based on violations observed during an inspection conducted from November 17, 2014 to December 18, 2014 (the "November-December 2014 Inspection"). The letter explained that Kwong Tung Foods' noodles and sprouts were adulterated within the meaning of 21 U.S.C. § 342(a)(4), and warned Defendants that failure to correct the violations could result in regulatory action, including an injunction. The Warning Letter also requested a written response

of corrective actions within fifteen days.

25. Defendants never responded to the April 9, 2015 Warning Letter.

26. Previously, on March 14, 2012, FDA met with Defendants in response to the facility's December 2010-January 2011 Inspection and FDA's August 22, 2011 Untitled Letter to Defendant Victor Wang. The letter documented the insanitary conditions at the firm, warned Defendants that their noodles and sprouts were adulterated within the meaning of 21 U.S.C. § 342(a)(4), and requested a written response from the Defendants describing the specific steps taken to correct the violations noted and assurances that similar violations would not occur. During this meeting, FDA emphasized the seriousness of the repeat violations observed at Defendants' facility and reiterated the need for them to address their violations.

27. At the conclusion of the meeting, Defendant Victor Wang acknowledged the seriousness of the violations discussed and committed to comply with the Act and its implementing regulations.

28. While Defendants have been warned repeatedly that the insanitary conditions at their facility could lead to regulatory action and an injunction, many of the conditions observed at Defendants' facility have persisted year after year.

29. Based on Defendants' persistent violations in the face of multiple prior warnings, Plaintiff is informed and believes that, unless restrained by order of the Court, Defendants will continue to violate 21 U.S.C. § 331(k).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each

and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of the Court's order from, directly or indirectly, violating 21 U.S.C. § 331(k), by doing and causing to be done any act that causes an article of food within the meaning of 21 U.S.C. § 321(f) to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), while such article is held for sale after shipment of one or more of its components in interstate commerce;

II. Order Defendants and each and all of their agents, representatives, employees, attorneys, successors, assigns, and any and all persons in active concert or participation with any of them (including individuals, directors, partnerships, corporations, subsidiaries, and affiliates) who receive notice of the Court's order to cease, directly or indirectly, receiving, processing, manufacturing, preparing, packaging, holding, and/or distributing any article of food at or from Defendants' facility (and any other or new location at or from which Defendants receive, process, manufacture, prepare, pack, hold, or distribute food), unless and until Defendants bring their operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

III. Award the United States its costs herein, including investigation costs, and such other relief as the Court may deem just and proper.

Dated this 14th day of July, 2016.

Respectfully submitted,

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(Pending Admission *Pro Hac Vice*)