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UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

SACRAMENTO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. HENH WONG FRESH PRODUCE, a sole proprietorship, DAVID C. LY, an individual doing business as Henh Wong Fresh Produce, THANH "DANNY" C. LY, an individual, and KIN S. LY, an individual, Defendants.	CASE NO. _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents to this Court as follows:

1. This action is brought by the United States of America pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin and restrain Henh Wong Fresh Produce, a sole proprietorship; David C. Ly, an individual doing business as Henh Wong Fresh Produce; Thanh "Danny" C. Ly, an individual; and Kin S. Ly, an individual (collectively, "Defendants"), from violating 21 U.S.C. § 331(k), by causing articles

of food that Defendants held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. §332(a) and 28 U.S.C. §§1331, 1337, and 1345, and personal jurisdiction over all parties. The defendants' actions cause articles of food held for sale, within this district, to become adulterated within the meaning of The Food Drug and Cosmetic Act, 21 U.S.C. § 342(a)(4).

3. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and (c). Henh Wong Fresh Produce is located at 2630 5th Street, Unit 92, Sacramento, California 95818, within the jurisdiction of this court.

DEFENDANTS

4. Defendant Henh Wong Fresh Produce ("the firm") is a sole proprietorship located at 2630 5th Street, Unit 92, Sacramento, California 95818. The firm manufactures and distributes tofu, seasoned tofu, fried tofu, fried bean cakes, soy jello, and soybean drinks. It also grows, harvests, prepares, packs, holds, and distributes ready-to-eat mung bean and soybean sprouts. In addition to manufacturing and distributing products under the name Henh Wong Fresh Produce, the firm also manufactures and distributes products as Henh Wong Fresh Product and Henh Wong Tofu.

5. Defendant David C. Ly is the owner and sole proprietor of Henh Wong Fresh Produce.

6. Defendant Thanh "Danny" C. Ly is the assistant manager of the firm. He is responsible for ordering, receiving, storing, processing, selling, and distributing raw materials and finished product. He has served as the assistant manager since 2012. During the 2014 inspection, Danny Ly informed investigators that he is the most responsible person at the firm. Investigators issued the List of Inspectional Observations ("Form FDA 483") to Danny Ly at the conclusion of the inspection and discussed the insanitary conditions and current good manufacturing practice ("cGMP") violations that they observed with him.

7. Defendant Kin S. Ly is Danny Ly's father and currently employed by the firm as a general laborer. From at least 2003 until 2012, Kin Ly served as the firm's general manager. During the 2003, 2005, 2008, 2010, and 2011 inspections, Kin Ly identified himself as the most responsible person at the firm. At the conclusion of each of these inspections, investigators issued Forms FDA 483 to Kin Ly and discussed the insanitary conditions and cGMP violations that they observed with him. During the 2014 inspection, FDA investigators observed Kin Ly handling sales, delivering finished product, and packing finished sprouts.

8. The tofu products and sprouts manufactured by Defendants are food within the meaning of 21 U.S.C. § 321(f). Thus, Defendants have been and are now engaged in receiving, preparing, processing, manufacturing, packing, holding, and distributing articles of food, within the meaning of 21 U.S.C. § 321(f).

9. Defendants' tofu products and sprouts are made from ingredients that have been shipped in interstate commerce. The firm receives the fried gypsum powder it uses in its tofu products (i.e., tofu, seasoned tofu, fried tofu, fried bean cakes, and soy jello) from Hong Kong. The firm also receives its mung bean and soybean sprout seeds from out-of-state suppliers in Kentucky and Minnesota.

DEFENDANTS' VIOLATIONS

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

11. Under the Act, food is deemed to be adulterated within the meaning of 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

12. Food processors must adhere to the cGMP requirements for manufacturing, packing, and holding human food. 21 C.F.R. Part 110. Failure to follow cGMP requirements renders food adulterated in violation of 21 U.S.C. § 342(a)(4). See 21 C.F.R. § 110.5(a).

13. As detailed in paragraph 15 below, Defendants' tofu products and sprouts are 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 whereby they may have been rendered injurious to health. Defendants have also violated § 342(a)(4) by failing to follow cGMP requirements. The violative conditions include, but are not limited to, Defendants' failure to take effective measures to exclude pests from the facility, failure to maintain equipment used to produce food in a sanitary manner, and failure to prevent insanitary employee practices.

INSPECTIONS

14. FDA's inspections of Defendants' facility have established that Defendants have an extensive history of preparing, packing, and holding food under insanitary conditions, in violation of the Act. See 21 U.S.C. § 342(a)(4). Additionally, the inspections have established that Defendants consistently fail to follow the food cGMP requirements. See 21 C.F.R. Part 110.

June–July 2014 Inspection

15. FDA most recently inspected Defendants' facility from June 30–July 16, 2014. During the inspection, FDA investigators observed numerous insanitary conditions and cGMP violations at Defendants' facility and documented their observations on a Form FDA 483. FDA investigators issued a Form FDA 483 to Defendants at the close of the inspection. During the inspection, FDA investigators observed insanitary conditions and cGMP violations in three main areas: (a) inadequate pest control, (b) inadequate equipment cleaning, and (c) poor employee practices. The violative conditions observed by FDA include, but are not limited to, the following:

a. Defendants failed to adequately exclude pests from the facility. Specifically, FDA investigators found: live cockroaches and flies in the tofu production room, a live cockroach inside a plastic container used for holding ready-to-eat tofu, dead cockroaches in the sprout processing room, a dead cockroach in the mung bean dry storage room, and rodent excreta pellets in the seed dry storage and sprout processing rooms. See 21 U.S.C. §342(a)(4), 21 C.F.R. §110.35(c).

b. Defendants failed to adequately maintain food production equipment in a sanitary manner. During the inspection, FDA investigators found: black residue on an icemaker lid that comes into direct contact with the ice used to cool packaged tofu; brownish residue on the exterior surface of the tofu press molds; and black residue and a mildew-like build-up on PVC pipes that come into direct contact with sprouts. Additionally, investigators documented an employee dragging a water hose across the floor and then placing it on the sprout shaker table. The employees use the sprout shaker table to remove small or broken sprouts and bean casings before they pack the sprouts into plastic bags. After employees removed the hose from the table, they failed to clean or sanitize the table before they resumed sprout processing. Investigators also witnessed an employee cleaning equipment with a scrub pad that had been sitting in standing water all day. See 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 110.35(d); 110.80(b)(2).

c. Defendants failed to prevent insanitary employee practices. FDA found numerous violative employee practices, including: employees using a high pressure hose to clean equipment and debris on the floor in the tofu production room, causing water to splash from the floor onto nearby fried tofu and other in-process tofu products; an employee touching the lid of a dumpster covered with a black slimy residue and old food build-up and then handling ready-to-eat tofu without sanitizing her hands; an employee scooping sprouts off the floor and then touching various food product contact surfaces without first changing or sanitizing his gloves; an employee using a dirty floor broom to clean sprout processing equipment; and an employee touching a scale stained with a black slimy residue and then continuing to pack ready-to-eat sprouts without first changing or sanitizing his gloves. See 21 U.S.C. § 342(a)(4); 21 C.F.R. §§ 110.35(d); 110.80(b)(2).

Previous Inspections

16. FDA inspected Defendants' facility five other times prior to the 2014 inspection—in 2003, 2005, 2008, 2010, and 2011. Similar to the 2014 inspection, FDA investigators observed questionable or violative practices during all of these inspections. The persistent violative practices include, but are not limited to, the following:

a. Defendants failed to exclude pests from the facility. For example, during the 2003, 2010, and 2011 inspections, investigators found insects or rodent excreta pellets in various locations throughout the facility.

b. Defendants failed to properly clean and sanitize food-processing equipment. Specifically, during every inspection, investigators found built-up residue on tofu and sprout processing equipment.

c. Defendants failed to prevent insanitary employee practices. For instance, during the 2003, 2005, 2010, and 2011 inspections, FDA investigators observed Defendants' employees handling tofu and sprout processing equipment with gloves and then not washing or sanitizing their gloves prior to handling food product or food contact surfaces.

NOTICE OF VIOLATIONS

17. FDA has given Defendants ample notice that they are producing food under insanitary conditions and violating cGMP requirements. At the conclusion of each inspection, FDA investigators provided Defendants with a Form FDA 483 that identified specific observations that were of concern to the investigators. FDA investigators also discussed their concerns with the individual most responsible for the firm at the time of the inspection—Kin Ly or Danny Ly.

18. In 2003, FDA issued a warning letter to Defendants that described some of the insanitary conditions and cGMP violations investigators observed at Defendants' facility during the 2003 inspection. The warning letter explained that Defendants' tofu and sprouts were adulterated within the meaning of 21 U.S.C. § 342(a)(4) and cautioned Defendants that failure to correct the violations could result in regulatory action, including injunction and/or seizure. Defendants never responded to the warning letter.

19. Additionally, after FDA's 2010 inspection, FDA held a regulatory meeting with Defendants. During the meeting, FDA reiterated to Defendants' representative the necessity of addressing the many violative conditions at the firm. FDA also discussed the agency's concern that laboratory testing of samples taken from the floor and equipment in the tofu processing room during the 2010 inspection had revealed the presence of the bacteria *Yersinia*

enterocolitica. The particular strain of *Yersinia enterocolitica* that FDA found is not injurious to human health, but its presence serves as an indicator that the conditions at the firm are conducive to the growth of pathogenic bacteria.

20. Defendants have promised corrections to some of the violative conditions at the conclusion of each inspection. Additionally, after the 2010 inspection, Kin Ly wrote a letter to FDA indicating that the firm planned to make the necessary corrections. Further, at the 2011 regulatory meeting, Defendants' representative also reiterated the firm's commitment to making corrections. Despite these promises, however, the firm has provided limited details on their improvements, failed to provide information on how the firm will sustain the improvements, and failed to provide details on how the firm will prevent future occurrences. Thus, while Defendants have corrected some of the violations, the firm's response as a whole has been inadequate and the firm has failed to maintain effective corrections. For instance, in the 2010 letter from Kin Ly, the general manager promised that the firm would begin completely washing and sanitizing all tofu processing equipment. Yet, during the 2014 inspection, investigators found black slimy residue and old food build-up on tofu processing equipment. Additionally, during the 2011 regulatory meeting, Defendants' representative promised that the firm would remove the pits in the floor, which can harbor pathogens, by leveling the cement floors in the facility. During the 2014 inspection, however, FDA found the floor of the sprout processing room heavily pitted and cracked.

21. Accordingly, Defendants have failed to institute the practices and procedures necessary to ensure that their facility prepares, packs, and holds food under sanitary conditions and does not violate cGMP requirements. Based on Defendants' repeated violations in the face of numerous 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 distributing any article of food within the meaning of 21 U.S.C. § 321(f), at or from Defendants' facility (and any other or new location at or from which Defendants receive, processes, manufacture, prepare, pack, hold, or distribute food) any article of 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 costs of investigation to date, and such other relief as the Court may deem just and proper.

Dated this 30th day of June 2015

Respectfully submitted,

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