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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. WA HENG DOU-FU & SOY SAUCE CORPORATION, a corporation, d/b/a WA HENG DOU-FU & SOY SAUCE INTERNATIONAL ENTERPRISES, and PENG XIANG "MARTIN" LIN, and YUEXIAO "OPAL" LIN, individuals, 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), and the inherent equitable authority of this Court, to permanently enjoin and restrain Wa Heng Dou-Fu & Soy Sauce Corporation, a corporation, d/b/a Wa Heng Dou-Fu & Soy Sauce International Enterprises, and Peng Xiang "Martin" Lin, and Yuexiao "Opal" Lin, individuals (collectively, "Defendants"), from violating 21 U.S.C. § 331(k), by causing articles of food that are 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) and misbranded within the meaning of 21 U.S.C. §§ 343(e), (q), and/or (r).

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.

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

DEFENDANTS

4. Defendant Wa Heng Dou-Fu & Soy Sauce Corporation ("Wa Heng Dou-Fu" or "the firm"), which also does business as Wa Heng Dou-Fu & Soy Sauce International Enterprises, is a California Corporation with its principal place of business at 2451 26th Ave #1, Sacramento, California ("the facility"), within the jurisdiction of this Court. Wa Heng Dou-Fu receives, prepares, processes, manufactures, labels, packs, holds, and distributes soy products.

5. Defendant Peng Xiang "Martin" Lin ("Martin Lin") is a co-owner and President of Wa Heng Dou-Fu. He is responsible for, among other things, the firm's daily operations, raw material purchases, facility and equipment maintenance, and production schedule. He performs his duties at the facility, within the jurisdiction of this Court.

6. Defendant Yuexiao "Opal" Lin ("Opal Lin") is a co-owner and Chief Financial Officer of Wa Heng Dou-Fu. Her responsibilities include, but are not limited to, managing the firm's finances, training employees, advertising, and overseeing employee performance. She performs duties at the facility, within the jurisdiction of this Court.

7. Defendants have been and are now engaged in receiving, preparing, processing, manufacturing, labeling, packing, holding, and distributing articles of food, within the meaning of 21

U.S.C. § 321(f), namely, soy products. Such products include, but are not limited to, fried tofu, firm tofu, seasoned tofu, and soy drinks.

8. Defendants' soy products are made from ingredients that have been shipped in interstate commerce, such as soybeans from Nebraska.

DEFENDANTS' VIOLATIONS OF THE ACT

9. 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 in interstate commerce.

10. As detailed in paragraph 16 below, recent FDA inspections establish that Defendants' soy products 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.

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

12. Defendants violate 21 U.S.C. § 331(k) by causing food to become misbranded, within the meaning of 21 U.S.C. §§ 343(e), (q), and/or (r), while it is held for sale after shipment in interstate commerce.

13. As detailed in paragraph 18 below, certain of Defendants' soy products are misbranded within the meaning of 21 U.S.C. §§ 343(e), (q), and/or (r) because the products': (1) label does not contain an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; (2) label or labeling does not bear nutrition information that provides information on specified nutrients; and/or (3) label or labeling bears a claim which expressly or by implication characterizes the level of any nutrient which is of the type required to be in the label or labeling of the food.

DEFENDANTS' HISTORY OF VIOLATIONS

14. Defendants have an extensive history of operating their food manufacturing facility under insanitary conditions, failing to follow the food cGMP requirements, and misbranding their food

products. FDA has documented Defendants' pattern of continuing violative conduct during FDA inspections in 2015, 2014, 2012, and 2011.

April 2015 Inspection

15. FDA conducted its most recent inspection of Wa Heng Dou-Fu between April 28 and April 30, 2015 (the "April 2015 Inspection").

16. During the April 2015 Inspection, FDA investigators observed insanitary conditions and documented violations that included, but were not limited to, Defendants':

(a) Failure to maintain buildings, fixtures, and physical facilities in a sanitary condition, as required by 21 C.F.R. § 110.35. For example, FDA investigators conducted environmental sampling of the facility, and five subsamples tested positive for pathogenic *Salmonella* ("*Salmonella* Havana"). The positive samples were taken from: a floor drain near the cooking tank, a caster wheel on a cart carrying tofu, a caster wheel on a tofu holding rack, a floor drain near the final packaging table, and the floor between the packing and processing rooms. This is a repeat violation. FDA isolated a nearly identical strain of *Salmonella* Havana during its 2012 and 2011 inspections.

(b) Failure to take reasonable precautions to ensure that production procedures do not contribute to contamination from any source, as required by 21 C.F.R. § 110.80. FDA investigators observed at least three employees spraying pressurized water from a water hose onto the production area floor, where FDA isolated *Salmonella* Havana, causing water to splash from the floor onto uncovered tofu and onto food-contact surfaces, such as tofu presses and a filtration table. This is a repeat observation from the 2012 inspection.

(c) Failure to wash and sanitize hands thoroughly in an adequate hand-washing facility at any time their hands may have become soiled or contaminated, as required by 21 C.F.R. § 110.10(b)(3). For example, FDA investigators observed employees touching the bottoms of buckets and crates that had been on the floor and then touching tofu. Additionally, the production room hand wash sink had no hot water because the hot water valve behind the sink had been turned off, and the sink was inaccessible because plastic crates were placed in front of it. This is a repeat observation from the 2012 inspection.

(d) Failure to maintain equipment and utensils in an acceptable condition through appropriate cleaning and sanitizing, as required by 21 C.F.R. § 110.80(b)(1). For example, investigators observed spray hose nozzles, air valves, water valves, and light switches that contained white, yellow, and brown heavy residue, and a tofu cutting knife that was placed on top of a tofu press machine with greenish-brown buildup and then used to slice tofu.

At the close of the April 2015 Inspection, an FDA investigator issued a Form FDA-483, List of Inspectional Observations ("Form FDA-483"), to Defendant Martin Lin. During a May 28, 2015, teleconference with Defendant Martin Lin, FDA investigators discussed the presence of *Salmonella* Havana at the facility, Defendants' repeated cGMP deficiencies, and the inadequate corrective actions Defendants' proposed to FDA.

17. Defendants responded to the Form-483 issued at the close of the April 2015 Inspection during the May 28, 2015, teleconference call with FDA representatives and in writing on June 1 and June 11, 2015. Defendants' responses contained promises to correct their unlawful conduct that were similar or, in some instances, identical to those Defendants previously made to FDA, but have repeatedly failed to keep. As evidenced by their continued violations, Defendants have failed to implement adequate corrective actions to address their cGMP violations.

18. During the April 2015 Inspection, an FDA investigator collected samples of Defendants' product labeling. Defendants' products are misbranded within the meaning of the Act, 21 U.S.C. §§ 343(e), (q), and (r), respectively, because:

(a) The soy products Hua Xing Seasoned Dou-Fu (hard, soft, Shanghai style, Taiwan style), Hua Xing Light Fried Dou-Fu, Hua Xiang Fried Dou-Fu (with mushroom), and Hu Xing Dou-Fu Fried Triangle fail to bear a label containing an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. See 21 U.S.C. § 343(e)(2). Specifically, these product labels bear a net quantity of contents statement containing the term "or more" after the net weight, which is not an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count and tends to exaggerate the amount of the food contained in the package. See id.; 21 C.F.R. §101.105(o);

(b) Defendants' soy products are intended for human consumption and are offered for sale, but some of their products' labels or labeling fail to bear nutrition information that provides specific information, such as serving size, calories, and the amount of certain nutrients. See 21 U.S.C. § 343(q). The product labels or labeling for Hua Xing Seasoned Dou-Fu (hard), Hua Xing Light Fried Dou-Fu, Hua Xing Fried Dou-Fu (with mushroom), and Hua Xing Dou-Fu Triangle fail to contain a statement of the caloric content per serving, such as total calories, as required by 21 C.F.R. § 101.9(c)(1). These product labels also list a "Serving Per Container" declaration of "3," with a "Serving Size" of "3 oz." and a "Net. Weight" of "12 oz.," but based on the listed serving size and net weight, servings per container should be "4" on all labels; and

(c) Defendants' soy products are intended for human consumption and are offered for sale, and their labels or labeling for Hua Xing Light Fried Dou-Fu bear a claim which expressly or by implication characterizes the level of a nutrient which is of the type required to be in the label or labeling of the food. See 21 U.S.C. § 343(r)(1)(A) (also setting forth exceptions inapplicable here). Specifically, Defendants' Hua Xiang Light Fried Dou-Fu bears the claim "light," but the claim fails to comply with the requirements for a "light" claim under 21 C.F.R. § 101.56.

Previous FDA Inspections and Warnings

19. Prior to the April 2015 Inspection, FDA inspected Wa Heng Dou-Fu on June 25, 2014, between October 30 and November 20, 2012, and between September 14 and September 26, 2011.

20. FDA's previous inspections documented cGMP and/or labeling violations that were the same as, or similar to, those described in paragraphs 16 and 18, including, but not limited to: failing to maintain buildings, fixtures, and physical facilities in a sanitary condition, as evidenced by the ongoing presence of *Salmonella* Havana; operating with poor employee practices, such as employees failing to wash their hands, in violation of 21 C.F.R. § 110.10(b)(3); and/or using food labeling that does not declare "an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count . . . .", as required by 21 U.S.C. § 343(e)(2). At the close of the 2011 and 2012 inspections, FDA investigators issued Forms FDA-483 listing the violations observed during the inspections to Defendant Martin Lin and discussed the observations with him.

21. On May 28, 2015, following the 2015 inspection, FDA representatives held a teleconference call with Defendant Martin Lin to discuss the positive *Salmonella* Havana samples that FDA found at the facility, Defendants' continued deviations, and inadequate corrective actions proposed by Defendants.

22. On December 3, 2012, following the 2012 inspection, FDA and California Department of Public Health representatives met with Defendants to discuss insanitary conditions at the facility, including the presence of *Salmonella* on a metal food tray only an inch away from seasoned tofu and on a floor drain located in a part of processing area with heavy foot traffic. The meeting followed a state embargo of all of Defendants' products, and their recall of all soy products on November 29, 2012, because of potential contamination with filth. State and FDA representatives informed Defendants that their corrective actions were inadequate and urged them to voluntarily remedy the insanitary conditions at the facility and their labeling deviations. An FDA representative also warned Defendants of the possibility of regulatory action if their violations continued.

23. On February 21, 2012, following the 2011 inspection, FDA issued a Warning Letter to Defendant Martin Lin describing Defendants' cGMP violations and stating that the violations caused Defendants' food to be adulterated within the meaning of 21 U.S.C. § 342(a)(4). The Warning Letter also explained that Defendants' labeling caused certain products to be misbranded within the meaning of 21 U.S.C. § 343. The Warning Letter urged Defendants to correct their violations, and stated that failure to promptly do so could result in regulatory action, including an injunction.

24. Despite FDA's warnings and Defendants' promises to correct the violations, Defendants have consistently failed to manufacture and label their products in compliance with the Act and its implementing regulations.

25. The findings from the April 2015 Inspection establish that Defendants continue to violate 21 U.S.C. § 331(k) by causing the adulteration and misbranding of food while held for sale after shipment of one or more components in interstate commerce.

26. The United States is informed and believes that, unless restrained by order of the Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set forth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and affiliates), from directly or indirectly doing or causing to be done any of the following acts:

(a) Violating 21 U.S.C. § 331(k), by causing food that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4); and/or

(b) Violating 21 U.S.C. § 331(k), by causing food that Defendants hold for sale after shipment of one or more of its components in interstate commerce to become misbranded within the meaning of 21 U.S.C. §§ 343(e), (q), and/or (r);

II. Order Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and affiliates) who receive notice of the Court's Order, to cease, directly or indirectly, receiving, preparing, processing, manufacturing, labeling, packing, and distributing all food at or from the facility, or any other or new location(s) at or from which Defendants receive, prepare, process, manufacture, label, pack, or distribute food, unless and until Defendants bring their receiving, preparing, processing, manufacturing, labeling, packing, and distribution 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 deems just and proper.

Dated: June 17, 2016

Respectfully submitted,

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