UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

vs. Civil Action No.

GREEN HOPE, LLC, a limited liability company, d/b/a ROSEWOOD PRODUCTS, and PHIL G. YE, an individual,

Defendants.
_____/

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

INTRODUCTION

1. This statutory injunction proceeding 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 enjoin and restrain Green Hope, LLC ("Green Hope"), d/b/a Rosewood Products, and Phil G. Ye, an individual (collectively, "Defendants"), from: (a) violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or the causing thereof, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4); and (b) violating 21 U.S.C. § 331(k), by causing articles of food to become 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 of their components in interstate commerce.

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

DEFENDANTS

3. Green Hope, LLC, d/b/a Rosewood Products, is a limited liability company organized under the laws of Michigan. Green Hope prepares, processes, packs, holds, and distributes primarily ready-to-eat ("RTE") organic tofu and soy milk products. Green Hope's manufacturing facility is located at 738 Airport Boulevard, Suite 6, Ann Arbor, Michigan 48108, within the jurisdiction of this Court.

4. Mr. Phil G. Ye is the owner of Green Hope. Mr. Ye has final authority over the day-to-day operations of Green Hope, including production, receiving, shipping, cleaning, and purchasing equipment and ingredients. Mr. Ye performs his duties at 738 Airport Boulevard, Suite 6, Ann Arbor, Michigan 48108.

5. All of Defendants' raw soybeans are shipped to Green Hope from Ohio, and Defendants ship some of their finished product to Minnesota.

DEFENDANTS' VIOLATIONS

6. Defendants violate 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or the causing thereof, articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

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

8. Defendants' products are food within the meaning of 21 U.S.C. § 321(f).

9. Defendants distribute their food products in interstate commerce.

10. Defendants receive soybeans used to make their products from a source located outside the state of Michigan, specifically, Ohio.

11. Defendants' RTE organic tofu and soy milk 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.

DEFENDANTS' HISTORY OF VIOLATIONS

12. Inspections of Defendants' facility by the United States Food and Drug Administration ("FDA") have established that Defendants are violating the Act.

November 2011 Inspection

13. FDA's most recent inspection of Green Hope was conducted between November 14-29, 2011. This inspection was conducted in follow-up to a previous violative inspection conducted in February and March 2011 and a Warning Letter, sent to Defendants on May 6, 2011.

14. The inspection revealed that Defendants had failed to implement effective corrections and uncovered further evidence of filth. Specifically, FDA investigators made observations, including, but not limited to:

(a) Defendants failed to prepare, process, and pack foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination as required by 21 C.F.R. § 110.80(b)(2). For example, investigators observed a piece of hair on packaged RTE tofu. Moreover, investigators observed an employee spray utensils close to the ground using a pressurized water hose. After the waste water hit the ground, the aerosolized

spray came in contact with the utensils. These utensils subsequently came in contact with RTE tofu during processing. Investigators also observed three employees with bare, unwashed arms reaching into and lowering racks of unwrapped RTE tofu into a cooling vat.

(b) Defendants' employees failed to wash their hands thoroughly in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when their hands may have become soiled or contaminated as required by 21 C.F.R. § 110.10(b)(3). For example, investigators observed Defendants' employees touching non-food contact surfaces such as mechanical switches, unwashed rags, and unwashed scoops, and then handling RTE tofu.

(c) Defendants failed to have smoothly bonded or maintained seams on food-contact surfaces to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms, as required by 21 C.F.R. § 110.40(b). Investigators observed that the outer surfaces of totes used for pressing and molding RTE tofu were rough and flaking, and that a pale residue adhered to the outer surface of the tote.

(d) Defendants failed to clean all food-contact surfaces, including utensils and food-contact surfaces of equipment, as frequently as necessary to protect against contamination of food as required by 21 C.F.R. § 110.35(d). For example, Defendants' employee admitted to FDA investigators that Defendants do not wash the crates used to store RTE tofu.

(e) Defendants failed to maintain buildings, fixtures, and physical facilities in repair sufficient to prevent food from becoming adulterated as required by 21 C.F.R. § 110.35(a). For example, investigators observed chipped paint on the walls in the processing area within one foot of a hopper containing raw soybeans. Investigators also observed mold on the wall in the

processing area, in close proximity to a hopper holding raw soybeans and a kettle holding unfiltered soy milk.

(f) Defendants failed to ensure that the plant is equipped with adequate sanitary facilities and accommodations, including, but not limited to, plumbing of adequate size and design and adequately installed and maintained to: (i) prevent backflow from, or cross-connection between, piping systems that discharge waste water or sewage and piping systems that carry water for food or food manufacturing as required by 21 C.F.R. § 110.37(b)(5); and (ii) provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor as required by 21 C.F.R § 110.37(b)(4). Investigators observed hoses that did not contain any type of backflow prevention device and standing water inside and outside of the walk-in cooler.

(g) Defendants failed to take effective measures to protect finished food from contamination by raw materials and other ingredients as required by 21 C.F.R. § 110.80(b)(6). Investigators observed that, during processing of RTE tofu, the same hose was submerged in barrels containing raw soybeans and later submerged in the cooling vat containing RTE tofu.

(h) Defendants failed to ensure that hand-washing facilities be furnished with running water at a suitable temperature as required by 21 C.F.R. § 110.37(e). Investigators observed that the sinks in the processing area had only cold running water.

15. At the close of the inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations ("Form FDA-483"), to Defendant Ye.

February/March 2011 Inspection

16. FDA conducted an inspection of Green Hope between February 28-March 16, 2011. This inspection was a follow-up to a previous violative inspection conducted in May 2010.

17. The inspection revealed that Defendants had failed to implement effective corrections and uncovered evidence of filth. Specifically, FDA investigators made observations, including, but not limited to:

(a) Failure to prepare, process, pack, and hold foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination; and

(b) Defendants' employees failed to wash their hands thoroughly in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when their hands may have become soiled or contaminated; and

(c) Failure to have smoothly bonded or maintained seams on food-contact surfaces so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms; and

(d) Failure to clean food-contact surfaces and utensils as frequently as necessary to protect against contamination of food; and

(e) Failure to maintain buildings, fixtures, and physical facilities in repair sufficient to prevent food from being adulterated; and

(f) Failure to ensure that plumbing is of adequate size and design and adequately installed and maintained to provide adequate floor drainage.

18. At the conclusion of the February/March 2011 inspection, FDA investigators issued a Form FDA-483 to Defendant Ye.

May 2010 Inspection

19. FDA conducted an inspection of Green Hope between May 19-25, 2010. This inspection was a follow-up to a November 5, 2009, regulatory meeting between FDA and Mr. Ye.

20. The inspection revealed that Defendants had failed to implement effective corrections and uncovered evidence of filth. Specifically, FDA investigators made observations, including, but not limited to:

(a) Failure to prepare, process, pack, and hold foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination; and

(b) Defendants' employees failed to wash their hands thoroughly in an adequate hand-washing facility before starting work, after each absence from the work station, and at any other time when their hands may have become soiled or contaminated; and

(c) Failure to have smoothly bonded or maintained seams on food-contact surfaces so as to minimize accumulation of food particles, dirt, and organic matter and thus minimize the opportunity for growth of microorganisms; and

(d) Failure to clean food-contact surfaces and utensils as frequently as necessary to protect against contamination of food; and

(e) Failure to maintain buildings, fixtures, and physical facilities in repair sufficient to prevent food from being adulterated; and

(f) Failure to ensure that plumbing is of adequate size and design and adequately installed and maintained to provide adequate floor drainage.

21. At the conclusion of the May 2010 inspection, FDA investigators issued a Form FDA-483 to Defendant Ye.

September 2009

22. FDA conducted an inspection of Green Hope between September 9-21, 2009. At the conclusion of the inspection, FDA investigators issued a Form FDA-483 to Defendant Ye that documented deficiencies similar to observations made by FDA investigators at subsequent inspections.

PRIOR WARNINGS

23. FDA issued Forms FDA-483 to Defendants after each inspection and discussed the documented violations with Defendant Ye. FDA also issued a letter to Defendants on May 6, 2011, warning them that FDA's February/March 2011 inspection revealed insanitary conditions at the facility that caused the food prepared, packed, and held there to be adulterated. The letter explained that it was Defendants' responsibility to correct those conditions. In addition, FDA held a regulatory meeting with Defendant Ye in November 2009 to discuss sanitation deficiencies. Moreover, the Michigan Department of Agriculture and Rural Development ("MDARD") repeatedly inspected Green Hope between 2009 and 2011. FDA and MDARD warned Defendants that they were operating under filthy conditions and that their failure to implement corrections could lead to regulatory action.

24. After the Warning Letter, and each of the inspections, Defendants promised in writing that they would correct their violations. Yet, as shown by the results of FDA's most recent inspection, Defendants' attempted corrective actions remain insufficient as they continue to violate the Act. Based on Defendants' repeated violations in the face of these warnings, and their numerous unfulfilled promises to institute effective, long-term corrections, Plaintiff is informed and believes that, unless restrained by order of the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), 331(k).

WHEREFORE, Plaintiff respectfully requests that this Court:

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

A. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction into interstate commerce any article of food that is adulterated; and

B. violating 21 U.S.C. § 331(k) by causing the adulteration of any article of food while such article is held for sale after shipment of one or more of its components in interstate commerce.

II. Permanently and perpetually restrain and enjoin, under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships), from doing or causing to be done, directly or indirectly, any act that adulterates food within the meaning of 21 U.S.C. § 342(a)(4).

III. Order Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) to cease, directly or indirectly, receiving, processing, manufacturing, preparing, packaging, holding, and distributing all food at or from their facilities, or any other or

new location(s) at or from which Defendants receive, process, manufacture, prepare, pack, hold, or distribute food, unless and until Defendants bring their receiving, processing, manufacturing, preparing, packaging, holding, and distributing operations into compliance with the Act and its implementing regulations to the satisfaction of FDA; and

IV. Grant the United States its costs and such other and further relief as the Court deems just and proper.

Dated: March 28, 2012

Respectfully submitted,

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