

UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES	OF AMERICA,)
	Plaintiff,) Civil Action No.
NEW RICH CITY TRADING CORPORAL a corporation, and XIAOPING and SI YAN CHUEN, individual Defendan	TRADING CORPORATION.	13 2945
	and XIAOPING SUN	A TRUE COPY CERTIFIED FROM THE RECORD MAY 2 9 2013
	Defendants.) ATTEST: Steve Tonco

COMPLAINT FOR PERMANENT INJUNCTION

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

INTRODUCTION

1. The United States brings this action under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin and restrain New Rich City Trading Corporation, Xiaoping Sun, and Si Yan Chuen (collectively, "Defendants"), from 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 held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

- This Court has subject matter jurisdiction under
 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 under 28 U.S.C. \$ 1391(b) and (c) as all defendants either reside in this district or did business in this district, and a substantial part of defendants' actions that give rise to this complaint all occurred in this district.

PARTIES

- 4. Plaintiff is the United States of America.
- 5. Defendant New Rich City Trading Corp. ("NRC"), is a Pennsylvania corporation that receives, holds, and distributes articles of food within the meaning of 21 U.S.C. § 321(f) at and from its principal place of business at 2650 N. American Street, Philadelphia, Pennsylvania (the "facility"), within the jurisdiction of this Court.
- 6. Defendant Xiaoping Sun is the owner and President of NRC. Defendant Sun has authority for all of NRC's operations, including purchasing, sales, personnel decisions, maintenance, and employee practices. Defendant Sun performs her duties at the facility, within the jurisdiction of this Court.
 - 7. Defendant Si Yan Chuen is the Manager and Foreman of

NRC. Defendant Chuen is responsible for NRC's receipt and distribution of food at and from the facility and he reports directly to Defendant Sun. Defendant Chuen performs his duties at the facility, within the jurisdiction of this Court.

DEFENDANTS' CONDUCT AND VIOLATIONS

- 8. Defendants violate 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 21 U.S.C. § 342(a)(4).
- Defendants' products are food within the meaning of 21
 U.S.C. § 321(f).
- 10. Defendants receive and hold for sale food that has been shipped in interstate commerce.
- 11. Defendants' food is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been held under insanitary conditions whereby it may become contaminated with filth or be rendered injurious to health. The insanitary conditions include Defendants' failure to take effective measures to exclude pests from the facility and to protect against the contamination of food with filth, as evidenced by, among other things, the presence of animals and animal waste throughout the facility (such as rodent, canine, feline, and avian), including on and around articles of food held at the facility.

FACTUAL BACKGROUND

12. Defendants have a history of operating the facility under insanitary conditions, despite numerous warnings by the United States Food and Drug Administration ("FDA"). This pattern of continuing violative conduct by Defendants has been documented in four FDA inspections since 2011.

FDA's November 2012 Inspection

- November 15 and 28, 2012, as a follow-up to prior violative inspections. (Ex. A, Form FDA 483, Inspectional Observations, 11/28/2012; Exs. B-1 and B-2, Photographs from FDA November 2012 Inspection.) During the November 2012 inspection, FDA investigators observed continuing insanitary conditions, which were discussed with Defendants Sun and Chuen, including, but not limited to, the following:
- (a) Defendants failed to take effective measures to protect against contamination of food with filth. The FDA investigators observed cats and dogs moving freely through the facility, as well as cat, dog, and rodent feces on and around Defendants' food, (Ex. A, Form FDA 483, Inspectional Observations, 11/28/2012); Exs. B-1 and B-2, Photographs from FDA November 2012 Inspection);
 - (b) Defendants failed to take effective measures to

exclude animals from the facility. The FDA investigator found multiple points for the ingress of animals and/or insects into the facility, including an exterior door left open by Defendants during operating hours and gaps between the facility's floor and external doors, (Ex. A, Form FDA 483, Inspectional Observations, 11/28/2012; Exs. B-1 and B-2, Photographs from FDA November 2012 Inspection); and

- (c) Defendants failed to maintain buildings, fixtures, and other facilities in a sanitary condition. For example, the FDA investigator observed litter, waste, standing water, exposed insulation, and uncut weeds in and around the facility, all of which may constitute attractants, breeding places, and/or harborages for pests. (Ex. A, Form FDA 483, Inspectional Observations, 11/28/2012; Exs. B-1 and B-2, Photographs from FDA November 2012 Inspection.)
- 14. The FDA investigators took photographs during the November 2012 investigation, and discussed their observations with Defendants. At the conclusion of the November 2012 inspection, the FDA issued an Inspectional Observation Report ("Form FDA 483") to the Defendants. (Ex. A, Form FDA 483, Inspectional Observations, 11/28/2012; Exs. B-1 and B-2, Photographs from FDA November 2012 Inspection.)

Defendants' History of Violating the Act

15. Defendants' history of violating the Act dates back to at least 2011. FDA previously inspected the facility in May 2011, September 2011, and June 2012 and, and has repeatedly warned Defendants about the violative conditions at their facility.

May 2011 Inspection

- 16. FDA conducted an inspection of the facility between May 24 and 25, 2011. (Ex. C, Form FDA 483, Inspectional Observations, 5/25/2011.)
- 17. The inspection revealed insanitary conditions, including, but not limited to, Defendants' failure to take effective measures to exclude animals from the facility. The FDA investigator noted rodent excreta in food storage areas and cats and dogs moving freely throughout the facility. (Ex. C, Form FDA 483, Inspectional Observations, 5/25/2011.)
- 18. The FDA investigator discussed the observations with Defendants, who promised to take corrective actions.
- 19. At the conclusion of the May 2011 inspection, the FDA issued a Form FDA 483 to Defendants. (Ex. C, Form FDA 483, Inspectional Observations, 5/25/2011.)

September 2011 Inspection

- 20. FDA conducted a follow-up inspection of the facility between September 13 and 20, 2011. (Ex. D, Form FDA 483, Inspectional Observations, 9/20/2011.)
- 21. The inspection revealed that the Defendants continued to operate under insanitary conditions, including, but not limited to, the following:
- (a) Defendants failed to take effective measures to exclude animals from the facility. The FDA investigator observed cats within the facility and cat and rodent excreta throughout the facility including on and around pallets of food, (Ex. D, Form FDA 483, Inspectional Observations, 9/20/2011); and
- (b) Defendants failed to adequately maintain the grounds of the facility. For example, the FDA investigator observed litter, weeds, and unused equipment around the facility, all of which may constitute attractants, breeding places, and/or harborages for pests. (Ex. D, Form FDA 483, Inspectional Observations, 9/20/2011.)
- 22. The FDA investigator discussed the observations with Defendants, who promised to take corrective actions.
- 23. At the conclusion of the September 2011 inspection, the FDA issued a Form FDA 483 to Defendants. (Ex. D, Form FDA 483, Inspectional Observations, 9/20/2011.)

June 2012 Inspection

- 24. FDA conducted another follow-up inspection of the facility between June 4 and 8, 2012. (Ex. E, Form FDA 483, Inspectional Observations, 6/8/2012.)
- 25. The inspection revealed continuing insanitary conditions including, but not limited to, the following:
- (a) Defendants failed to take effective measures to protect against contamination of food with filth. The FDA investigators noted rodent and bird excreta throughout the facility, including on food held in the facility, as well as cats and dogs moving freely throughout the facility, (Ex. E, Form FDA 483, Inspectional Observations, 6/8/2012);
- (b) Defendants failed to take effective measures to exclude animals from the facility. The FDA investigators found multiple points for the ingress of animals and/or insects into the facility, including an exterior door left open by Defendants during operating hours and gaps between the facility's floor and external doors, (Ex. E, Form FDA 483, Inspectional Observations, 6/8/2012); and
- (c) Defendants failed to maintain buildings, fixtures, and other facilities in a sanitary condition. For example, the FDA investigators observed litter, waste, exposed insulation, and uncut weeds in and around the facility, all of which may

constitute attractants, breeding places, and/or harborages for pests. (Ex. E, Form FDA 483, Inspectional Observations, 6/8/2012.)

- 26. The FDA investigators discussed the observations with Defendants, who again promised to take corrective actions.
- 27. At the conclusion of the June 2012 inspection, the FDA issued a Form FDA 483 to Defendants. (Ex. E, Form FDA 483, Inspectional Observations, 6/8/2012.)
- 28. FDA issued a Warning Letter to Defendant Sun on July 3, 2012, stating that sanitation issues throughout the facility, such as the widespread presence of animals, and animal feces and urine, caused food held therein to be adulterated within the meaning of 21 U.S.C. § 342(a)(4). (Ex. F, July 3, 2012 FDA Warning Letter.)
- 29. The Warning Letter informed Defendants that if corrective measures were not taken, Defendants could be subject to further legal action, including the seizure of food or the shutdown of the facility. (Ex. F, July 3, 2012 FDA Warning Letter.)
- 30. Despite FDA's efforts and warning, Defendants have consistently failed to hold food in compliance with the Act and its implementing regulations. The findings from FDA's most recent inspection in November 2012 establish that Defendants

continue to violate 21 U.S.C. § 331(k) by causing the adulteration of food while held for sale after shipment of one or more of its components in interstate commerce.

31. Based on Defendants' history of violations despite warnings, the United States is informed and believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set forth above.

FIRST CAUSE OF ACTION

Violation of the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331(k)

- 32. The United States re-alleges and incorporates by reference the above paragraphs as though set forth fully herein.
- 33. Defendants violate 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 21 U.S.C. § 342(a)(4).
- 34. Unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set forth above.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully requests this Court:

- I. Permanently and perpetually restrain and enjoin Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and each and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's Order, from directly or indirectly violating 21 U.S.C. § 331(k) by causing the adulteration of any article of food while such article of food 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 equitable authority of this Court, Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, heirs, attorneys, and each 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, heirs, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of the Court's Order, to cease receiving, holding, and/or distributing all food at or from the facility, or any other location(s) at or from which Defendants receive, hold, or distribute food, unless and until Defendants bring their receiving, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of the FDA.

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

Dated this 29 day of May, 2013.

Respectfully submitted,

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TABLE OF EXHIBITS

- Ex. A. Form FDA 483, Inspectional Observations, 11/28/2012
- Ex. B-1. Photographs from FDA November 2012 Inspection
- Ex. B-2. Photographs from FDA November 2012 Inspection
- Ex. C Form FDA 483, Inspectional Observations, 5/25/2011
- Ex. D Form FDA 483, Inspectional Observations, 9/20/2011
- Ex. E. Form FDA 483, Inspectional Observations, 6/8/2012
- Ex. F July 3, 2012 FDA Warning Letter