

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA,)	
)	
Plaintiff,)	Civil Action
)	
v.)	
)	
NEW RICH CITY TRADING CORPORATION,)	
a corporation, and XIAOPING SUN)	
and SI YAN CHUEN, individuals,)	
)	
Defendants.)	No. 13-2945 LDD

~~CONSENT DECREE OF PERMANENT INJUNCTION~~

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a complaint for injunctive relief against Defendants New Rich City Trading Corporation ("NRC"), Xiaoping Sun, and Si Yan Chuen (collectively "Defendants"), and Defendants without admitting or denying the allegations of the Complaint having appeared and having consented to entry of this Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree;

IT IS HEREBY STIPULATED, ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The complaint for injunction states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. §§ 301 et seq.

3. The Complaint alleges that Defendants violate section 21 U.S.C. § 331(k) of the Act by causing articles 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 held for sale after shipment of one or more components in interstate commerce.

4. Defendants are hereby subject to the following requirements:

A. Within five (5) calendar days after entry of this Decree, Defendants shall retain, at their expense, an independent person(s) (the "Sanitation Expert") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, and experience, is qualified to develop and implement a written sanitation control program that will protect food and food-packaging materials from contamination from any source, including, but not limited to, filth, and determine whether Defendants comply with the Act, and

its implementing regulations, including, but not limited to, the current good manufacturing practice ("cGMP") requirements for food, see 21 C.F.R. pt. 110. Defendants shall notify the United States Food and Drug Administration ("FDA") in writing of the name(s) and qualifications of the Sanitation Expert as soon as they retain such expert;

B. Within ten (10) calendar days after entry of this Decree, the Sanitation Expert shall develop a written sanitation control program (the "Program") for Defendants' receiving, holding, and distributing articles of food, as described in paragraph 4.A. and shall submit such plan to FDA;

C. FDA will provide either a written approval of the Program or a written explanation of the Program's deficiencies. IF FDA requires Defendants to resubmit the Program to show correction of identified deficiencies, Defendants shall submit the corrected Program to FDA within ten (10) calendar days after receipt of the written explanation of the Program's deficiencies. FDA will review the corrected Program and provide written approval or further explanation of any new or remaining deficiencies. Defendants shall respond to each written explanation of deficiencies within ten (10) calendar days after receipt of the explanation.

D. Defendants shall make the FDA-approved Program available and accessible to all their employees in each language spoken by their employees;

E. Defendants shall assign responsibility and authority for implementing and monitoring the FDA-approved Program on a continuous basis to an employee who is trained in sanitation control requirements and qualified to implement and monitor the FDA-approved Program;

F. Within ten (10) calendar days after receiving the written approval of the Program described in paragraph 4.C., the Sanitation Expert shall conduct a comprehensive inspection of Defendants' food warehouse facility located at 2560 N. American Street, Philadelphia, Pennsylvania (the "facility") and Defendants' methods and controls used to receive, hold, and distribute food to determine whether:

i. Defendants have effectively established and implemented the FDA-approved Program;

ii. Defendants have established practices and procedures to ensure that their food will not be adulterated within the meaning of 21 U.S.C. § 342(a)(4);

iii. Defendants have corrected each and all observations listed on Forms FDA 483 issued to Defendants since

2011; and

iv. Defendants comply with the Act and its implementing regulations, including, but not limited to, the cGMP requirements for food;

G. Within twenty (20) calendar days after the inspection described in paragraph 4.F. is completed, the Sanitation Expert shall prepare and submit concurrently to FDA and Defendants a written report of the inspection, which shall include a list of observed deviations, if any, from compliance with the FDA-approved Program, the Act, and its implementing regulations, including, but not limited to, the cGMP requirements for food;

H. Within ten (10) calendar days after receiving the report described in paragraph 4.G., Defendants shall notify FDA and the Sanitation Expert in writing of the actions they have taken to correct each and all deviations listed in the Sanitation Expert's report, if any;

I. FDA, as it deems necessary, may inspect the facility to evaluate Defendants' compliance with this Decree, the Act, and its implementing regulations. The costs of FDA inspections conducted pursuant to this paragraph shall be borne by Defendants at the rates specified in paragraph 9; and

J. Defendants shall recall and destroy, under FDA supervision and in accordance with all applicable federal, state, and local laws, all food, except for food in impermeable containers, held and distributed at or from Defendants' facilities prior to the date this Decree is signed by the parties.

5. Within sixty (60) calendar days after entry of this Decree, Defendants shall retain, at Defendants expense, an independent person(s) (the "Auditor") with no personal or financial ties (other than the retention agreement) to Defendants or their families, except that the Auditor may be the same person as the Sanitation Expert, who is qualified by education, training, and experience to assess Defendants' compliance with the Act and its implementing regulations, including, but not limited to the cGMP requirements for food. Thereafter:

A. The Auditor shall conduct audit inspections of the facility to evaluate whether Defendants are in compliance with this Decree, the Act and its implementing regulations. Such audit inspections shall be conducted not less than once every six months for a period of one year and not less than once every twelve months for a period of four years thereafter, for a

total of five years of auditing.

B. At the conclusion of each audit inspection, the Auditor shall prepare a written report identifying in detail any objectionable conditions at the facility that could render articles of food held therein adulterated within the meaning of 21 U.S.C. § 342(a)(4). The reports shall be delivered to the Defendants and FDA no later than twenty (20) calendar days after the date each audit inspection is completed.

C. If a report identifies objectionable conditions, Defendants shall, within ten (10) calendar days of receipt of the report, make all necessary corrections. If Defendant concludes that corrective action cannot be achieved within ten (10) calendar days, Defendants shall notify FDA in writing of the basis for its conclusion and a proposed schedule for completing the corrective actions that does not exceed thirty (30) calendar days. Defendants shall make the corrections in accordance with the proposed schedule, unless FDA notifies Claimant in writing that a shorter time frame is required.

D. Within ten (10) calendar days of the required completion date for corrective actions, the Auditor shall review the corrective actions taken by Defendants and report in writing to FDA whether each objectionable condition has been corrected. If

such report identifies one or more objectionable condition that has not been corrected, FDA may, in its discretion, require up to five additional years of annual audits.

6. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) (collectively, "Associated Persons") who receive actual notice of this Decree, are

permanently restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from, directly or indirectly, doing or causing any act that:

A. Violates 21 U.S.C. § 331(k), by causing articles 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 articles are held for sale after shipment of one or more of their components in interstate commerce; and/or

B. Results in the failure to implement and continuously maintain the requirements of this Decree.

7. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the facility, and any other locations at or from which Defendants

receive, hold, and/or distribute articles of food and, without prior notice, to take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' articles of food, containers, and packaging material; and to examine and copy all records related to receiving, holding, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

8. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide

any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) calendar days after providing a copy of this Decree to a prospective successor or assign.

9. Defendant NRC shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to FDA within thirty (30) calendar days of receiving written notification from FDA of the costs. As of the date that this Decree is signed by the parties, these rates are: \$87.57 per hour and fraction thereof per representative inspection work; \$104.96 per hour or fraction thereof per representative analytical or review work; \$0.565 per mile for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the

standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

10. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, sample, analyses, or other information, that Defendants have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing and order Defendants to take appropriate action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease receiving, holding, and/or distributing any articles of food;

B. Recall all articles of food that have been distributed and/or are under the custody and control of Defendants' agents, distributors, customers, or consumers;

C. Submit samples of articles of food to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, or filth; and/or

D. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendant NRC shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, review, travel, and subsistence expenses to implement and monitor recalls and other actions, at the rates specified in paragraph 9 of this Decree.

11. The following process and procedures shall apply when FDA issues an order under paragraph 10, except as provided in subparagraph D below:

A. Unless a different time frame is specified by FDA in its order, Defendants shall, within ten (10) business days after receiving such order, notify FDA in writing that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's order. If Defendants notify FDA that they do not agree with

FDA's order, Defendants shall explain in writing the basis for their disagreement; in so doing, Defendants may propose specific alternative actions and specific time frames for achieving FDA's objectives.

B. If Defendants notify FDA that they do not agree with FDA's order, FDA will review Defendants' notification and thereafter, in writing, affirm, modify, or withdraw its order, as FDA deems appropriate. If FDA affirms or modifies its order, it shall explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action.

C. If FDA affirms or modifies its order, Defendants shall, upon receipt of FDA's order, immediately implement the order (as modified, if applicable), and if they so choose, bring the matter before this Court on an expedited basis. Defendants shall continue to diligently implement FDA's order, unless the Court sets aside, stays, reverses, vacates, or modifies FDA's order. Any review of FDA's decision under this paragraph shall be made in accordance with the terms set forth in paragraph 14 of this Decree.

D. The process and procedures set forth in paragraph 11A.-C. shall not apply to any order issued under paragraph 10

if such order states that, in FDA's judgment, the matter raises significant public health concerns. In such case, Defendants shall immediately and fully comply with the terms of that order. Should Defendants seek to challenge any such order, they may petition this Court for relief.

12. Should any Defendant fail to comply with the Act, its implementing regulations, or any provision of this Decree, including any time frame imposed by this Decree, then Defendant NRC shall pay to the United States of America: one thousand dollars (\$1,000) in liquidated damages for each day such violation continues; and an additional sum of one thousand dollars (\$1,000) in liquidated damages per day, per violation for each violation of the Act, its implementing regulations, and/or this Decree. Defendant NRC shall, in addition to the foregoing, pay an additional sum in liquidated damages equal to the retail value of any distributed articles of food that are adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

13. If any Defendant violates this Decree and is found in contempt thereof, such Defendant shall, in addition to other

remedies, reimburse Plaintiff for its attorneys' fees, travel expenses incurred by attorneys and witnesses, expert witness fees, administrative and court costs, investigation and analytical expenses incurred in bringing the contempt action, and any other costs or fees related to the contempt proceedings.

14. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before the FDA at the time the decision was made. No discovery shall be taken by either party.

15. Defendants shall post a copy of this Decree in each language spoken by their employees prominently in an employee common area at Defendants' facility within ten (10) calendar days after the entry of this Decree and shall ensure that the Decree remains posted for a period of at least six (6) months.

16. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree to each and all of the Associated Persons. Defendants shall provide to FDA within thirty (30) calendar days after the date of the entry

of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

17. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, attorneys, or any additional persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such persons. Within ten (10) calendar days of each instance that Defendant becomes associated with any such individual persons, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts. Within ten (10) calendar days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this

paragraph, Defendants shall provide such information or documentation to FDA.

18. Defendants shall address all communications required under this Decree to Director, Philadelphia District Office, United States Food and Drug Administration, U.S. Customhouse, 2nd & Chestnut Sts., Room 900, Philadelphia, PA 19106, and shall reference this civil action by case name and civil action number in such communications.

19. No sooner than five (5) years after entry of this Decree, Defendants may petition FDA for leave to ask this Court for relief from this Decree. If, at the time of the petition, in FDA's judgment, Defendant has maintained a state of continuous compliance with this Decree, the Act, and its implementing regulations for at least five (5) years, Plaintiff will not oppose the petition, and Defendants may request the Court to grant such relief.

20. This Court retains jurisdiction of this action and the parties hereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary and appropriate.

SO ORDERED:

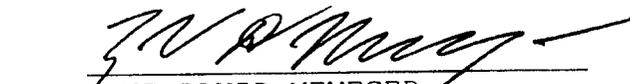
Dated this 27th day of June, 2013.

/s/ Legrome D. Davis

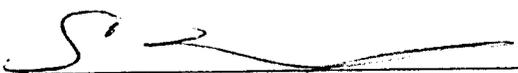
HONORABLE LEGROME D. DAVIS
UNITED STATES DISTRICT JUDGE

We hereby consent to the entry of the foregoing Decree.

Dated: 6/25/13


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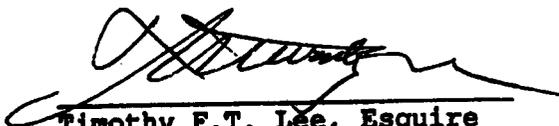
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President and Owner of New Rich City Trading Corporation,
individually and on behalf
of New Rich City Trading
Corporation Dated: 6-20-13



SI YAN CHUEN,
Manager and Foreman of New Rich City Trading Corporation,
individually Dated: 6-20-13



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