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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.	CIVIL ACTION NO. 2:15-cv-1403-CKD CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint For Permanent Injunction against Henh Wong Fresh Produce, David C. Ly, Thanh "Danny" C. Ly, and Kin S. Ly (collectively, "Defendants"), and Defendants having appeared and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

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

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

3. Defendants violate the Act, 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. The articles of food 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.

4. Upon entry of this Decree, Defendants represent to the Court that Defendants are not directly or indirectly engaged in manufacturing, processing, packing, labeling, holding, and/or distributing any articles of food from the facility at 2630 5th Street, Unit 92, Sacramento, California 95818, or from any other location. Defendants also represent to the Court that Henh Wong Fresh Produce has ceased all operations and production, and has completed the dissolution process. Defendants have neither transferred nor sold any business assets or equipment, nor assigned any assets to third parties. If any Defendant later intends to resume operations at 2630 5th Street, Unit 92, Sacramento, California 95818, or any other location, Defendants must first notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations and must comply with paragraphs 5(A) through (M) of this Decree. This notice shall identify the type(s) of food Defendants intend to receive, prepare, process, pack, label, hold, and/or distribute, and the facility in which Defendants intend to resume operations. Defendants shall not resume operations until FDA has first inspected Defendants' facility and operations pursuant to paragraph 5(L), Defendants have paid the costs of such inspection(s) pursuant to paragraph 5(M), and Defendants have received written notice from FDA, as required by paragraph 5(N), and then shall resume such food operations only to the extent authorized in FDA's written notice.

5. 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 actual notice of this Decree (collectively, "Associated Persons"), are hereby permanently restrained and enjoined, under 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, manufacturing, labeling, packing, holding, or distributing any food from or at the facility at 2630 5th Street, Unit 92, Sacramento, California 95818 and any other or new locations at which Defendants now, or in the future, directly or indirectly receive, prepare, process, manufacture, label, pack, hold, and/or distribute food (collectively, "Defendants' facility"), unless and until all of the following occur:

A. Defendants retain, at their expense, an independent person or persons (the "Sanitation Expert") who is without any personal or financial ties (other than the retention agreement) to Defendants or their families, and who, by reason of background, education, training, or experience, is qualified to develop and implement a written sanitation control and food safety plan ("Sanitation Control and Food Safety Plan"), covering Defendants' tofu and sprout manufacturing processes, cleaning and sanitizing operations, pest control, employee health and hygiene precautions, and plant construction and maintenance (including the plant's buildings and sanitation-related systems, equipment, and utensils contained therein) that will protect food, food contact surfaces, and food-packaging materials from contamination from any source including, but not limited to, chemicals, toxins, microorganisms, filth, and vermin;

B. Defendants notify FDA in writing of the name and qualifications of the Sanitation Expert as soon as they retain such expert;

C. Defendants' Sanitation Expert, after review of all FDA observations from July 2003 to present, develops an effective written Sanitation Control and Food Safety Plan (in English and Chinese) which shall, at a minimum:

i. Establish adequate methods, facilities, and controls for receiving, processing, manufacturing, preparing, packing, holding, and/or distributing articles of food to minimize the risk of contamination of food, food contact surfaces, and food packaging

materials, and to ensure that foods are not adulterated within the meaning of 21 U.S.C. § 342(a)(4). Such methods, facilities, and controls shall include, but shall not be limited to, thoroughly cleaning, sanitizing, renovating, and rendering Defendants' facility and all equipment therein suitable for use in receiving, processing, manufacturing, preparing, packing, holding, and distributing articles of food to prevent the articles of food from becoming adulterated; instituting standard sanitation operating procedures ("SSOPs"); instituting a cleaning and sanitizing schedule; and instituting monitoring and record-keeping procedures to ensure that Defendants' facility and equipment therein are continuously maintained in a sanitary condition;

ii. Ensure that Defendants adhere to the current good manufacturing practice ("cGMP") requirements, see 21 C.F.R. Part 110;

iii. Require that the adequacy of cleaning and sanitizing be routinely verified through targeted environmental swabbing and appropriate microbial testing;

iv. Require that seeds and beans used for sprouting are conditioned, stored, and transported in a manner that minimizes the likelihood that they will be contaminated with pathogens; that seeds are stored in closed or covered containers in a clean, dry area dedicated to seed and bean storage; and that containers are positioned off the floor and away from walls to reduce the possibility of contamination by rodents or other pests, and to facilitate regular monitoring for pest problems;

v. Require that seeds and beans used for sprouting be treated with one or more scientifically valid treatments to reduce pathogens in seeds or sprouts immediately prior to sprouting, and that Defendants monitor and control the parameters of the scientifically valid treatment(s);

vi. Require Defendants to conduct microbiological testing of spent irrigation water from each production lot to ensure that contaminated product is not distributed. Defendants must obtain the test results before shipping product and shall not ship any product from a production lot where contamination is found;

vii. Establish written procedures for remedial action should any pathogenic organism be detected;

viii. Establish a written employee training program (in English and Chinese) that includes, at a minimum, instruction in sanitation control requirements for food-handling and manufacturing, and documentation that each employee has received such training. Defendants' Sanitation Expert shall test to confirm that each employee fully understands the substance of the employee training program;

D. FDA approves, in writing, the Sanitation Control and Food Safety Plan;

E. Defendants make written copies of the Sanitation Control and Food Safety Plan available and accessible to all of their employees;

F. Defendants assign continuing responsibility for implementing and monitoring the Sanitation Control and Food Safety Plan to a person(s), who, by reasons of background, education, training or experience, is competent to maintain Defendants' facility in a sanitary condition, coordinate with the laboratory, and implement any necessary remedial action(s), and provide such person with the authority to achieve the necessary corrections;

G. Defendants complete a training program developed per paragraph 5(C)(viii), that includes, at a minimum, instructions in sanitation control requirements for food handling and manufacturing, and Defendants document that each employee has received such training;

H. Defendants develop and implement a system to facilitate traceback and recalls in the event of a violation or the potential for food-borne illness, and Defendants test their system to ensure that it will be adequate;

I. The Sanitation Expert conducts a comprehensive inspection of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein, to determine whether Defendants have: adequately established and implemented the Sanitation Control and Food Safety Plan; adequately addressed FDA investigators' inspectional observations listed on each Form FDA

483 issued to Defendants since July 2003 and any other violations noted by any state authority; and are operating in compliance with this Decree, the Act, and its implementing regulations. The Sanitation Expert should submit all findings to Defendants and FDA concurrently within ten (10) calendar days of completion of the inspection;

J. The Sanitation Expert certifies in writing to FDA that Defendants:

i. Have a copy of the FDA approved Sanitation Control and Food Safety Plan and have adequately established and implemented it;

ii. Have adequately addressed the Form FDA 483 observations; and

iii. Have complied with the cGMP requirements for food, see 21 C.F.R. Part 110;

K. Within thirty (30) calendar days after entry of this Decree, Defendants destroy, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved by FDA in writing prior to implementation, all raw ingredients and in-process and finished articles of food currently in their custody, control, or possession as of the date this Decree is signed by the parties;

L. FDA, as it deems necessary to evaluate Defendants' compliance with the terms of this Decree, the Act, and its implementing regulations, conducts inspections of Defendants' facility, including the buildings, sanitation-related systems, equipment, utensils, all articles of food, and relevant records contained therein;

M. Defendants have paid all costs of inspection(s), analysis, review, investigation(s), examination, and supervision for FDA's oversight with respect to paragraphs 5(A) through (L), at the rates set forth in paragraph 10 below; and

N. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 5(A) through (M) of this Decree, the Act, and its implementing regulations.

6. Upon resuming operations after completing the requirements of paragraph 5, Defendants shall continuously and effectively implement on an ongoing basis, the Sanitation

Control and Food Safety Plan developed pursuant to paragraph 5(C). In the event that Defendants or their Sanitation Expert determine that the sanitation control program needs to be revised, Defendants shall provide suggested changes to FDA in writing at least twenty (20) calendar days prior to their planned implementation, and shall not implement their suggested changes until FDA approves those changes in writing.

7. Notwithstanding paragraphs 4–6 of this Decree, Defendant Kin Ly may participate in receiving, preparing, processing, manufacturing, labeling, packing, holding, or distributing food for any corporation, partnership, firm, company, business, entity, and/or persons ("the Employer"), other than the remaining Defendants or any entity controlled, directly or indirectly, by any of the remaining Defendants, as long as the following conditions are met:

A. Defendant Kin Ly may only be employed or otherwise engaged with the Employer in receiving, preparing, processing, manufacturing, labeling, packing, holding, or distributing any type of food, in a non-management capacity (e.g., as a general laborer or production employee).

B. Defendant Kin Ly may not be employed by or otherwise engaged in receiving, preparing, processing, manufacturing, labeling, packing, holding, or distributing any type of food with any of the remaining Defendants or any entity controlled, directly or indirectly, by any of the remaining Defendants.

C. Before becoming employed or otherwise engaged in receiving, preparing, processing, manufacturing, labeling, packing, holding, or distributing any type of food, Defendant Kin Ly must notify and provide a copy of this Decree to the Employer.

D. Defendant Kin Ly shall provide FDA an affidavit at least ten (10) business days prior to becoming employed by or otherwise engaged with the Employer, and such affidavit shall include the name and address of the Employer and identify the names, addresses, and positions of all persons at the Employer who Defendant Kin Ly notified and provided a copy of this Decree.

E. In addition to the affidavit required in paragraph 7(D), Defendant Kin Ly shall also provide to FDA an affidavit with a detailed description of his employment duties within ten (10) business day of beginning his employment. If Defendant Kin Ly's employment duties change during the course of his employment with the Employer, Defendant Kin Ly shall provide to FDA an affidavit detailing his new employment duties within ten (10) business days of assuming his new duties.

8. Defendants and each and all of the 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.

9. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' facility and operations, and 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, raw ingredients, finished and unfinished materials and products, containers, labeling, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, finished and unfinished materials and products, containers, labeling, packaging material, and other material; and to examine and copy all records related to receiving, preparing, processing, manufacturing, labeling, packing, holding, and distributing any and all of Defendants' products. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate

credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses that FDA deems necessary to evaluate Defendants' compliance with any part of this Decree, at the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to FDA within twenty (20) business 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: $89.35 per hour and fraction thereof per representative for inspection or investigative work; $107.09 per hour or fraction thereof per representative for analytical or review work; $0.575 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. 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.

11. Within ten (10) business days after the date of Defendants' notice to FDA as described in paragraph 4, Defendants shall post a copy of this Decree (in English and Chinese) prominently in an employee common area at Defendants' facility and shall ensure that this Decree remains posted for as long as this Decree remains in effect. Within fifteen (15) business days after the date of Defendants' notice to FDA as described in paragraph 4, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph.

12. Within ten (10) business days after the date of Defendants' notice to FDA as described in paragraph 4, Defendants shall hold a general meeting or series of smaller meetings for all employees, at which they shall describe the terms and obligations of this Decree. Within fifteen (15) business days after the date of Defendants' notice to FDA as described in paragraph

4, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph, and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

13. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to each and all of the Associated Persons. Defendants shall provide to FDA within twenty (20) business days after the date of the entry of this Decree an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph, identifying the names, addresses, and positions of all persons so notified, and attaching a copy of the executed certified mail return receipts.

14. In the event that any Defendant becomes associated with any additional Associated Person(s) 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 Associated Person(s). Within ten (10) business days of each instance that any Defendant becomes associated with any additional Associated Person, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, 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) business 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.

15. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name, or character of their business, including incorporation, 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 to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

16. 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, preparing, processing, manufacturing, labeling, packing, 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 raw ingredients, and in-process and finished 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 that 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. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence

expenses to implement and monitor recalls and other actions, at the rates specified in paragraph 10 of this Decree.

17. Upon receipt of any order issued by FDA pursuant to paragraph 16, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in paragraph 16 shall be implemented immediately upon notice from FDA and shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. After a cessation of operations, and while determining whether Defendants are in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Decree.

18. If any Defendant fails to comply with the provisions of this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages in the sum of five thousand dollars ($5,000) for each day that Defendants fail to comply with this Decree, an additional sum of five hundred dollars ($500) in liquidated damages per day for each violation of this Decree, the Act, and/or its implementing regulations, and an additional sum equal to twice the retail value of each shipment of adulterated food. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States to seek, and the Court to impose, additional civil or criminal penalties based on the conduct that may also be the basis for payment of the liquidated damages.

19. If any Defendant violates this Decree and is found in contempt thereof, Defendants 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.

20. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, if challenged, 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 FDA at the time the decision was made. No discovery shall be taken by either party.

21. All notifications, correspondence, and communications to FDA required by the terms of this Decree shall be prominently marked "Decree Correspondence" and addressed to District Director, San Francisco District Office, United States Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, California 94502, and shall reference this civil action by case name and civil action number.

22. 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, this 3rd day of August, 2015.

UNITED STATES DISTRICT JUDGE
Carolyn K. Delaney
U.S. Magistrate Judge

Entry consented to:

For Defendants

HENH WONG FRESH PRODUCE,
a sole proprietorship

DAVID C. LY,
in his individual capacity and as sole proprietor of Henh Wong Fresh Produce

THANH "DANNY" C. LY.
in his individual capacity

KINSLY, in his individual capacity

For Plaintiff

Dated this 30th day of June, 2015

Respectfully submitted,

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Of Counsel:

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ACKNOWLEDGMENT

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California }
County of SACRAMENTO }

On 6/22/15 before me, JOSEPH MAITA - NOTARY PUBLIC
(here insert name and title of the officer)

personally appeared DAVID C LY, THANH C. LY &
KIM S. LY

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____

(Seal)

JOSEPH MAITA
Commission # 2059440
Notary Public - California
Sacramento County
My Comm. Expires Feb 14, 2018