UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA,

Plaintiff,

v.

FOO YUAN FOOD PRODUCTS COMPANY, INC.,
HSING CHUANG (aka George Chuang),
and SUSAN CHUANG,

Defendants.

Civil Action No.
18-CV-4689
(Vitaliano, J.)
(Pollak, M.J.)

DEFAULT JUDGMENT AND ORDER PURSUANT TO FED. R. CIV. P. 55

On August 20, 2018, plaintiff, the United States of America, by its attorney, Richard P. Donoghue, United States Attorney for the Eastern District of New York, and Edwin Cortes, Assistant United States Attorney, and Monica Groat, Trial Attorney for the Department of Justice, having commenced this action against Foo Yuan Food Products Company, Inc., Hsing Chuang (aka George Chuang), and Susan Chuang (collectively, the "Defendants"), by filing of a complaint and the issuance of summonses;

This action being brought pursuant to 21 U.S.C. § 332(a) alleging that the Defendants were currently violating 21 U.S.C. §§ 331(a) and 331(k), provisions of the Federal Food, Drug, and Cosmetic Act (the "Act") by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated (§ 331(a)) and by causing food to become adulterated while such food is held for sale after shipment of one or more of its components in interstate commerce (§ 331(k));

The United States seeking permanent injunctive relief enjoining the Defendants from violating the Act;

A copy of the complaint and the summonses having been served on all Defendants on September 11, 2018; and proof of service having been filed with the Office of the Clerk of the Court;

The Defendants having failed to answer or otherwise respond to the complaint, or to defend this action;

The Clerk of the Court having entered Notation of Default on November 15, 2018; and

Upon the pleadings, papers, and proceedings herein to date;

NOW, on the motion of the United States, it is hereby

ORDERED AND ADJUDGED that judgment by default is entered against the Defendants in favor of the United States pursuant to Fed. R. Civ. P. 55, and that, pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act") and the inherent power of this Court:

1. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority, and has personal jurisdiction over all parties to this action.

2. The Complaint states a cause of action against Defendants under the Act.

3. Defendants violate the Act, 21 U.S.C. § 331(a), by causing the introduction or delivery for introduction into interstate commerce food, within the meaning of 21 U.S.C. § 321(f), namely fish and fishery products, that is adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, packed, or held under insanitary conditions

whereby it may have become contaminated with filth or may have been rendered injurious to health.

4. Defendants violate the Act, 21 U.S.C. § 331(k), by causing food within the meaning of 21 U.S.C. § 321(f), namely fish and fishery products, to become adulterated within the meaning of 21 U.S.C. § 342(a)(4), in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health, while such food is held for sale after shipment in interstate commerce.

5. Upon entry of this Order, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities) (hereinafter, collectively referred to as "Associated Persons"), who have received actual notice of this Order by personal service or otherwise, are hereby permanently restrained and enjoined under 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, labeling, holding, and/or distributing any article of food at or from their facility located at 2301 Borden Ave., Long Island City, NY 11101, or any other location(s) at which Defendants now or in the future directly or indirectly receive, prepare, process, pack, label, hold, and/or distribute articles of food (referred to as "Defendants' Facility" or "the Facility"), unless and until:

A. Defendants retain, at their expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and that is qualified to analyze product and

environmental samples collected at the facility for the presence of *Listeria monocytogenes* ("*L. mono*"), in a manner that is acceptable to the United States Food and Drug Administration ("FDA"); and

B. Defendants retain, at their expense, an independent expert or experts (the "Expert(s)") having no personal or financial ties (other than a retention agreement) to Defendants or their families, and who, by reason of background, education, training, or experience, is qualified to:

i. Conduct hazard analyses to develop adequate written Hazard Analysis Critical Control Point ("HACCP") plan(s) for Defendants' fish and fishery product(s), as required by 21 C.F.R. § 123.6(a) through (c);

ii. Verify and ensure the adequacy of Defendants' written HACCP plan(s) in accordance with paragraph 5(C)(i-iv) below ;

iii. Develop adequate written Sanitation Standard Operating Procedures ("SSOPs") in accordance with paragraph 5(C)(v) below;

iv. Develop a Listeria Monitoring Program in accordance with paragraph 5(C)(vi) below;

v. Collect product samples, and environmental samples from within the facility for pathogen testing in accordance with paragraph 5(C) below;

vi. Evaluate Defendants' compliance with the current good manufacturing practice ("cGMP") requirements as required by 21 C.F.R. Part 110;

vii. Develop and conduct employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the SSOPs, seafood HACCP and cGMP requirements, and Listeria Monitoring Program; and

viii. Inspect the facility and determine whether the methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Order;

Defendants shall notify the FDA in writing of the identity and qualifications of the Laboratory under paragraph 5(A) and Expert(s) under paragraph 5(B) within three (3) business days of retaining such Laboratory and Expert(s) and shall provide FDA with a copy of the service contract with the Laboratory. The service contract shall contain provisions, acceptable to FDA, for environmental and finished product sample analyses;

C. After reviewing all FDA inspectional observations of deficiencies from October 2014 to the present, Defendants' Expert(s), in conjunction with Defendants, shall:

i. Conduct hazard analyses and develop, to FDA's satisfaction, adequate written HACCP plan(s), as required by 21 C.F.R. § 123.6, for each type of fish and/or fishery product received, prepared, processed, packed, labeled, held, and/or distributed by Defendants, that at a minimum, effectively controls food safety hazards, including but not limited to (i) those associated with *Clostridium botulinum* ("*C. bot.*") growth and toxin formation likely to occur in reduced oxygen packaged fish and fishery products under normal and

moderate temperature abuse conditions, and (ii) those associated with pathogen growth and toxin formation in ready to eat product likely to occur from a cook step that does not achieve a minimum 6 log reduction of *L. mono*.

ii. Verify and ensure the adequacy of Defendants' written HACCP plan(s), as described in 21 C.F.R. § 123.8, to FDA's satisfaction, including but not limited to conducting scientific validation studies for the adequacy of the critical limits listed in Defendants' written HACCP plan(s), including validation studies to ensure product packaged in reduced oxygen packaging achieves and maintains activity levels that are consistently below 0.97 to adequately control *C. bot.* and for cooking validation studies that include heat penetration and heat distribution cook to control pathogen growth and toxin formation by consistently achieving at least a 6-log reduction of *L. mono*.

iii. Develop, to FDA's satisfaction, written corrective action plans as part of Defendants' written HACCP plan(s) to be implemented whenever there is a deviation from a critical limit, as described in 21 C.F.R. 123.7(b);

iv. Develop, to FDA's satisfaction, written verification procedures as part of Defendants' written HACCP plan(s), as described in 21 C.F.R. § 123.8;

v. Develop, to FDA's satisfaction, written SSOPs specific to Defendants' facility and operations and that shall conform with the procedures set forth at 21 C.F.R. § 123.11(a) through (d), and ensure, to FDA's satisfaction, that Defendants' operations comply with the Act and 21 C.F.R. Part 110;

vi. Develop and implement, to FDA's satisfaction, a written Listeria Monitoring Program that shall include, at a minimum, the following:

(1) an effective written sanitation control program that establishes adequate methods, facilities, and controls for receiving, preparing, processing, packing, labeling, holding, and distributing articles of food to minimize the risk of introducing *L. mono,* other pathogenic organisms, and filth into Defendants' food, and to ensure that foods are not adulterated within the meaning of 21 U.S.C. § 342(a);

(2) an effective program for environmental monitoring and testing of the facility to ensure that organisms such as *Listeria* species ("*L. spp.*") are systemically controlled and that pathogenic organisms such as *L. mono* do not occur in finished products. Sampling should be conducted using specified frequencies and methods (e.g., including how, where, and when to sample; the number and frequency of samples to be collected; and the methods of analyses) that are acceptable to FDA. Defendants shall ensure that the results of all analyses conducted pursuant

to (C)(vi)(2) are sent to FDA within two (2) calendar days after receipt by Defendants; and

(3) an adequate written plan for remedial action that Defendants shall implement should *L. spp.* or any pathogenic organism, including *L. mono*, be detected. The remedial action shall include, at a minimum, product disposition, intensified sanitation, intensified sampling measures and, upon repeat findings, a contamination source determination (root cause analysis), all of which are acceptable to FDA.

vii. Develop and conduct, to FDA's satisfaction, employee training programs (in English and any other language necessary to effectively convey the substance of the training) on the seafood HACCP regulations, cGMP regulations, FDA-approved written HACCP plan(s), SSOPs, and Listeria Monitoring Program, and any other control strategies specific to Defendants' fish and fishery products, and documents that Defendants and each of their officers, employees, and any other person(s) who perform duties at Defendants' facility have received such training; and

viii. Submit to FDA the written HACCP plan(s) and all associated records (including monitoring records), validation studies, SSOPs, the Listeria Monitoring Program, written verification procedures, and employee training programs and documentation developed pursuant to paragraph 5(C)(i)-(vii) above; and documentation demonstrating

that the Expert(s) have trained Defendants and each of their officers, employees, and any other persons who perform duties at Defendants' facility as described in paragraph 5(C)(vii) above;

D. FDA has approved, in writing, the written HACCP plan(s) and all associated records (including monitoring records), validation studies, SSOPs, Listeria Monitoring Program, written verification procedures, and employee training programs and documentation developed by the Expert(s) as specified in paragraph 5(C) above;

E. Defendants take the following additional actions:

i. Assign continuing responsibility for implementing and monitoring the FDA-approved SSOPs and Listeria Monitoring Program to a person (or persons) who, by reason of background, education, training, or experience, is qualified to maintain Defendants' facility in a sanitary condition, coordinate with the Laboratory, and implement any necessary corrective action(s), and Defendants provide such person with the authority to achieve any necessary corrective action;

ii. Ensure that the FDA-approved written HACCP plan(s), Listeria Monitoring Program, and SSOPs are available and accessible (in English and any other language necessary to effectively convey the substance of such documents) to their officers, employees, and any other persons who perform duties;

iii. Successfully administer an FDA-approved employee training program; and

iv. At their expense, clean and sanitize their facility and equipment therein and make improvements, thereby rendering their facility and equipment suitable for receiving, preparing, processing, packing, holding, labeling, and distributing articles of food in accordance with this Order, the Act, and all applicable regulations, and Defendants ensure that their facility and equipment therein will be continuously maintained in a sanitary condition.

F. The Expert(s) conducts a comprehensive inspection of Defendants' facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute food to determine whether Defendants are operating in compliance with this Order, the Act, and all applicable regulations. Defendants shall require that the Expert(s) verify, with supporting documentation, that (i) Defendants have corrected all of the seafood HACCP and cGMP deficiencies observed by FDA since October 2014, specifying each FDA observation and Defendants' corrections thereof; (ii) the monitoring equipment used to implement Defendants' written HACCP plan(s) is suitable and performing adequately; and (iii) Defendants' facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute articles of food are, in the Expert's opinion, in compliance with this Order, the Act, and its implementing regulations. The Defendants shall ensure that the Expert(s) submit, in writing, all findings and supporting documentation to Defendants and FDA concurrently, within fifteen (15) business days after completion of the inspection;

G. Defendants recall and destroy, under FDA's supervision and in accordance with the procedures provided in paragraph 5(H), all of Defendants' products that were manufactured, prepared, packed, labeled, held, and/or distributed one year prior to the date of entry of this Order;

H. Within thirty (30) calendar days after entry of this Order, Defendants shall 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 in-process and finished articles of food currently in their custody, control, or possession, if any, as of the date this Order is entered;

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

J. Defendants have paid all costs of inspection, analysis, review, investigation, examination, and supervision for FDA's oversight with respect to paragraphs 5(A) - (I), at the rates set forth in paragraph 13; and

K. FDA has notified Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraphs 5(A) - (J) of this Order, the Act, and its implementing regulations. In no circumstance shall FDA's silence be construed as a substitution for written notification.

6. After receiving notice from FDA pursuant to paragraph 5(K), Defendants shall not receive, prepare, process, pack, hold, label, or distribute any other fish or fishery product for

which the Defendant does not have an FDA approved HACCP plan(s) until Defendants submit for FDA's review written HACCP plan(s) for such fish or fishery product and receive FDA's written approval for such plan(s). In no circumstance shall FDA's silence be construed as a substitution for written approval.

7. Immediately upon resuming operations after completing the requirements of paragraph 5, Defendants shall, in consultation with the Expert(s), continuously implement the written HACCP plan(s), SSOPs, Listeria Monitoring Program, written verification procedures, and employee training programs approved by FDA pursuant to paragraph 5(D). Defendants further shall comply with the following requirements:

A. Defendants shall conduct finished product testing for *L. mono* in reduced oxygen packaged product in the following manner:

i. A randomly collected, representative sample from every lot of fish or fishery products that they process for the first five (5) consecutive production days;

ii. After the completion of testing under paragraph 7(A)(i), Defendants shall have tested a randomly collected, representative sample from one lot of each type of finished fish or fishery products that they process each week for the next three (3) months;

iii. After the completion of testing under paragraph 7(A)(ii), Defendants shall have tested a randomly collected, representative sample from at least one lot of each type of finished fish or fishery products that they process each month for the next twelve (12) months; and

iv. After completion of testing under paragraph 7(A)(iii), Defendants shall have tested a randomly collected, representative sample from at least one lot of each type of finished fish or fishery products that they process every three (3) months thereafter.

B. Defendants shall conduct finished product testing for water activity level in reduced oxygen packaged product in the following manner:

i. A randomly collected, representative sample from every batch of fish or fishery products that they process for the first five (5) consecutive production days;

ii. After the completion of testing under paragraph 7(B)(i), Defendants shall have tested a randomly collected, representative sample from one batch of each type of finished fish or fishery products that they process each week for the next three (3) months;

iii. After the completion of testing under paragraph 7(B)(ii), Defendants shall have tested a randomly collected, representative sample from at least one batch of each type of finished fish or fishery products that they process each month for the next twelve (12) months; and

iv. After completion of testing under paragraph 7(B)(iii), Defendants shall have tested a randomly collected, representative sample from at least one batch of each type of finished fish or fishery products that they process every three (3) months thereafter.

C. Defendants shall send copies of the results of all testing conducted pursuant to paragraphs 7(A) and (B) to FDA within two (2) calendar days after receipt by

Defendants. If any laboratory test completed pursuant to paragraphs 7(A) and (B) shows the presence of *L. mono* or an inadequate water activity level in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also recall and destroy, at Defendants' expense, under FDA's supervision, and according to a destruction plan submitted to and approved by FDA in writing prior to implementation, all food products manufactured from the time the laboratory sample(s) testing positive for *L. mono* or was found to have an inadequate water activity level was collected. Defendants may resume production only when they have determined and corrected the cause of the contamination or inadequate water activity level and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Order, the Act, and its implementing regulations. After correcting the cause of the contamination or inadequate water activity level, Defendants shall reinstate the complete sequence of testing under paragraphs 7(A) or (B) anew;

D. In the event that Defendants or their Expert(s) determine that the Listeria Monitoring Program that FDA approved pursuant to paragraph 5(D) needs to be revised, Defendants shall provide proposed changes to FDA in writing at least twenty (20) calendar days prior to their implementation, and shall not implement their proposed changes until FDA approves those changes in writing. Any such changes shall consist of methods and controls that are shown to FDA's satisfaction to systematically control *L. spp.* and ensure that *L. mono* does not occur in finished products.

8. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analyses pursuant to paragraph 5(A), Defendants terminate or in any way alter their service contract with the laboratory, Defendants shall notify FDA within seven (7) calendar days and promptly retain a new laboratory. If Defendants terminate their service contract, Defendants shall provide a copy of the service contract with the new laboratory to FDA within five (5) business days after contract execution.

9. Within thirty (30) calendar days after Defendants resume their operations after completing the requirements of paragraph 5 and receiving the notice set forth in paragraph 5(K), the Expert(s) shall conduct a comprehensive inspection of the facility, and any other location(s) at or from which Defendants receive, prepare, process, pack, hold, or distribute articles of food, and the methods and controls used to receive, prepare, process, pack, hold and distribute foods to determine whether Defendants are operating in compliance with this Order, the Act, and all applicable regulations. Defendants shall ensure that the Expert(s) submits a report documenting all findings to Defendants and FDA concurrently, within ten (10) calendar days after completing the inspection. Thereafter, the Expert(s) shall conduct one inspection every three (3) months for one year, and one inspection every six (6) months for the next two (2) years. Beginning in the fourth year after Defendants resume their operations after completing the requirements of paragraph 5, the Expert(s) shall conduct inspections annually unless FDA informs Defendants in writing that more frequent expert inspections and reporting are required. During each inspection conducted by the Expert(s), the Expert(s) shall verify that the facility and the methods and controls Defendants use to receive, prepare, process, pack, hold, or distribute articles of food are in compliance with the requirements of this Order, the Act, and all applicable regulations, and shall certify compliance in the Expert's report. If the Expert's report contains any observations

indicating that Defendants are not in compliance with this Order, the Act, or its implementing regulations, Defendants shall make all necessary corrections within ten (10) business days after receipt of the Expert's report, unless FDA notifies Defendants in writing that a shorter time period is necessary.

10. Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, affiliates, franchisees, and "doing business as" entities), who receive actual notice of this Order 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 the Act, 21 U.S.C. § 331(a), by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce, any article of food within the meaning of 21 U.S.C. § 342(a)(4);

B. Violates the Act, 21 U.S.C. § 331(k), by causing any article 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 article is held for sale after shipment of one or more components in interstate commerce; and/or

C. Results in the failure to implement and continuously maintain the requirements of this Order.

11. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect Defendants' facility, and any other location(s) at or from which Defendants receive, prepare, process, pack, hold, 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

Order, the Act, and its implementing regulations. During such inspections, FDA shall be permitted to: (i) have immediate access to buildings and the contents therein, including equipment, raw ingredients, in-process and finished articles of food, containers and packaging material; (ii) take photographs and make video recordings; (iii) take samples of Defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and (iv) examine and copy all records relating to receiving, preparing, processing, packing, holding, and distributing any and all articles of food and their components. The inspections shall be permitted upon presentation of a copy of this Order and appropriate credentials. The inspection authority granted by this Order is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

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

A. Cease receiving, preparing, processing, packing, holding, and distributing any articles of food;

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

C. Revise, modify, expand, or continue to submit any reports, plans, procedures, or other records prepared pursuant to this Order;

D. Submit additional reports or information to FDA as requested;

E. Submit additional samples to a qualified laboratory for analysis;

F. Institute or re-implement any of the requirements set forth in this Order;

G. Issue a safety alert; and/or

H. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Order, the Act, or its implementing regulations.

The provisions of this paragraph shall be separate and apart from, and in addition to, any other remedy available to FDA. Defendants shall pay all costs of recalls and other corrective actions, including the costs of FDA's supervision, inspections, investigations, supervision, analyses, examinations, sampling, testing, reviews, document preparation, travel, and subsistence expenses to implement and monitor the remedies set forth in this paragraph, at the rates specified in paragraph 13.

13. Defendants shall pay all costs of FDA's inspections, investigations, supervision, analyses, examinations, sampling, testing, and reviews that FDA deems necessary to evaluate Defendants' compliance with any part of this Order at the standard rates prevailing at the time the costs are incurred. 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 Order is entered, these rates are: $95.39 per hour or fraction thereof per representative for inspection and investigative work; $114.33 per hour or fraction thereof per representative for analytical or review work; $0.545 per mile for travel expenses by automobile; government rate

or the equivalent for travel by air or other means; and the published government per diem rate 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.

14. Upon receipt of any order issued by FDA pursuant to paragraph 12, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 12 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 Order, the Act, and its implementing regulations, and that Defendants may resume operations. After a cessation of operations, and while determining whether Defendants appear to be in compliance with the Order, the Act, and its implementing regulations, FDA may require Defendants to re-institute or re-implement any of the requirements of this Order.

15. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, preparing, processing, packing, labeling, holding, and/or distributing of Defendants' products. Defendants shall maintain copies of their written HACCP plan(s), along with copies of all records required by such plan(s), 21 C.F.R. Part 123, or this Order, at Defendants' facility, and any other location(s) at or from which Defendants receive, prepare, process, pack, hold, and/or distribute articles of food, in a location where such records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three (3) years after the date the records are prepared.

16. If any Defendant fails to comply with any provision of this Order, the Act, or its implementing regulations, including any time frame imposed by this Order, then Defendants

shall pay to the United States of America liquidated damages in the sum of one thousand dollars ($1,000) for each day such violation continues, and an additional sum in liquidated damages equal to twice the retail value of any shipment of articles of food that is adulterated or otherwise in violation of this Order, the Act, or its implementing regulations. 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 conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

17. Should the United States bring and prevail in a contempt action to enforce the terms of this Order, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), expert witness fees, travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, administrative and court costs, and any other costs or fees relating to such contempt proceedings.

18. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Order shall be vested in FDA's discretion and, if contested, shall be reviewed by this 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 Order 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.

19. Within five (5) calendar days after entry of this Order, Defendants shall prominently post a copy of this Order (in English and any other language necessary to effectively convey the substance of the Order) in a conspicuous location in an employee common area at Defendants' facility and shall ensure that the Order remains posted for as long as the Order remains in effect.

Within ten (10) business days after entry of this Order, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of compliance with this paragraph.

20. Within ten (10) calendar days after entry of this Order, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Order (in English and any other language necessary to effectively convey the substance of the Order). Within fifteen (15) business days after entry of this Order, Defendants shall provide to FDA an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of 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.

21. Within ten (10) calendar days after entry of this Order, Defendants shall provide a copy of the Order by personal service or certified mail (return receipt requested) to each and all of their Associated Persons and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Within thirty (30) calendar days after entry of this Order, Defendants shall provide to FDA 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.

22. In the event that any of the Defendants becomes associated with any additional Associated Person(s), 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 Order, Defendants shall immediately provide a copy of this Order, by

personal service or certified mail (return receipt requested) to such persons. Within ten (10) calendar days after each instance that any Defendant becomes associated with any such 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 compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Order pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

23. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of their business that occurs after entry of this Order, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, lease, sale, or any other change in the structure or identity of Foo Yuan Food Products Company, Inc., or the assignment, lease, or sale of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Order. Defendants shall provide a copy of this Order to any prospective successor or assign at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

24. Defendants shall address all communications required under this Order to the Director, Food and Drug Administration, New York District Office, 158-15 Liberty Avenue, Jamaica, NY 11433. All such communications to FDA required by the terms of this Order shall reference this civil action by case name and civil action number, and shall be prominently marked "Order Correspondence."

25. This Order resolves only the claims in this statutory injunction action brought under 21 U.S.C. § 332(a) as set forth in the complaint. Entry of this Order does not preclude any other

civil, criminal, or administrative claims that the government may have or may bring in the future against any of the Defendants herein in connection with, or relating to, any of the Defendants' activities involving FDA-regulated products, including the conduct alleged in the complaint filed with this Order.

26. Except as provided in the foregoing provisions of this Order, the parties shall bear their own costs and attorneys' fees in this action.

27. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Order and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED

Dated: November 11, 2019
Brooklyn, New York

s/ Eric N. Vitaliano
Honorable Eric N. Vitaliano
United States District Judge