PHILLIP A. TALBERT
Acting United States Attorney
COLLEEN M. KENNEDY
Assistant United States Attorney
501 I Street, Suite 10-100
Sacramento, CA 95814
Telephone: (916) 554-2700
Facsimile: (916) 554-2900

BENJAMIN C. MIZER
Principal Deputy Assistant Attorney General
JONATHAN F. OLIN
Deputy Assistant Attorney General
MICHAEL S. BLUME
Director, Consumer Protection Branch
RAQUEL TOLEDO
Trial Attorney, Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044
Telephone: (202) 532-4719
Facsimile: (202) 514-8742

Attorneys for Plaintiff
United States of America

IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. WA HENG DOU-FU & SOY SAUCE CORPORATION, a corporation, d/b/a WA HENG DOU-FU & SOY SAUCE INTERNATIONAL ENTERPRISES, and PENG XIANG "MARTIN" LIN, and YUEXIAO "OPAL" LIN, individuals, Defendants.	CASE NO. 2:16-CV-01358-KJM-CKD **CONSENT DECREE OF PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, having filed a Complaint for Permanent Injunction against Wa Heng Dou-Fu & Soy Sauce Corporation, a corporation, d/b/a Wa Heng Dou-Fu & Soy Sauce International Enterprises, and Peng Xiang "Martin" Lin, and Yuexiao

"Opal" Lin, individuals (collectively "Defendants"), and Defendants, without admitting or denying the allegations in the Complaint, 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. §§ 301–399f (the "Act").

3. The Complaint alleges that 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 components in interstate commerce.

4. The Complaint alleges that Defendants violate the Act, 21 U.S.C. § 331(k), by causing certain articles of food, within the meaning of 21 U.S.C. § 321(f), to become misbranded within the meaning of 21 U.S.C. §§ 343(e), (q), and/or (r), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

5. Upon entry of this Decree, 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 inherent equitable authority of this Court, from directly or indirectly receiving, preparing, processing, manufacturing, labeling, packing, holding, and/or distributing any articles of food at or from 2451 26th Ave #1, Sacramento, California 95822-2269, or at or from any other locations at which Defendants, now or in the future, directly or indirectly receive, prepare, process, manufacture, label, pack, hold, and/or distribute any articles of food (collectively, "the facility"), including but not limited to 1305 Furneaux Road, Olivehurst CA 95961 (the "Furneaux Road Facility"), unless and until:

A. Defendants retain, at their expense, an independent person or persons (the "Sanitation and Food Safety Expert(s)") who are without any personal or financial ties (other than the retention agreement) to Defendants or their families or operations, and who, by reason of background, education, training, or experience, are qualified to develop and implement a written sanitation and pathogen monitoring program in accordance with paragraph 5(B) below, to inspect Defendants' facility, and determine whether the methods, facilities, and controls are continuously operated and administered in conformity with this Decree, the Act, and its implementing regulations. Defendants shall notify FDA in writing of the name(s) and qualifications of the Sanitation and Food Safety Expert(s) as soon as they retain such expert(s);

B. Defendants' Sanitation and Food Safety Expert(s), after reviewing all of FDA's observations from September 2011 to the present, prepare a written sanitation and pathogen monitoring program (the "Program"). Within seven (7) business days after the Sanitation and Food Safety Expert(s) finish writing the Program, Defendants shall submit the Program to FDA. The Program shall ensure that Defendants' manufacturing processes, cleaning and sanitizing operations, pest control, corrective actions, employee health and hygiene precautions, and facility construction and maintenance (including the facility's buildings and sanitation-related systems (e.g., plumbing, sewage disposal), equipment, and utensils contained therein) protect against the contamination of food and food-contact surfaces and prevent insanitary conditions at the facility to FDA's satisfaction and shall address, but not be limited to, the growth of microorganisms and the presence of filth. FDA shall endeavor to complete its review of the Program submitted to FDA by Defendants and provide written feedback to Defendants about the adequacy of the Program in a timely manner. The Program shall, at minimum:

i. Require cleaning and sanitizing of utensils, equipment, carts, and floors, as well as monitoring and recordkeeping of the same on a daily basis when operating;

ii. Verify the adequacy of daily cleaning and sanitizing using generalized microbial testing, such as aerobic plate count or adenosine triphosphate ("ATP") testing;

iii. Establish corrective actions for any positive findings that result from Defendants' generalized microbial testing, including the disposal of articles of food produced on food-

contact surfaces that yielded positive findings, corrective actions to restore clean and sanitary conditions, and cleaning and sanitizing procedures to investigate the cause of any positive findings; and

iv. Establish monitoring and testing procedures to ensure that pathogenic organisms, including, but not limited to, *Salmonella* spp., are adequately controlled in the facility by, at a minimum, developing: (a) a schedule for regularly collecting swab samples from food-contact and non-food-contact surfaces, equipment, and other environmental sites throughout the facility where in-process and finished articles of food are received, processed, manufactured, prepared, packed, held, and/or distributed, and a facility map designating the locations for collecting swab samples; (b) a plan for testing all environmental samples for *Salmonella* spp.; (c) a plan for testing all environmental samples for *Listeria* spp., including *Listeria monocytogenes*; (d) a corrective action plan for responding to samples that yield pathogens; and (e) a plan to report the results of all positive test analyses conducted pursuant to this paragraph to FDA within two (2) calendar days of receiving such results and to retain all other test results conducted pursuant to this paragraph for FDA inspection;

C. Ensure that Defendants comply with current good manufacturing practice ("cGMP") in manufacturing, packaging, or holding food, 21 C.F.R. Part 110;

D. Establish a written employee training program 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 and Food Safety Expert(s) shall confirm and record that each employee fully understands the substance of the employee training program;

E. Defendants make the Program available and accessible to all their employees in a language each employee understands;

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

G. The Sanitation and Food Safety Expert(s) conduct a comprehensive inspection of the facility and Defendants' methods and controls used to receive, prepare, process, manufacture, pack, hold, and distribute articles of food to determine whether Defendants have adequately established and

implemented the Program, whether Defendants have adequately addressed the FDA investigators' inspectional observations listed on each Form FDA-483 issued to Defendants since September 2011, and whether Defendants comply with this Decree, the Act, and its implementing regulations, including the cGMP requirements for food;

H. Within twenty (20) business days after the inspection described in paragraph 5(G) is completed, the Sanitation and Food Safety Expert(s) prepare and submit contemporaneously to FDA and Defendants, by courier service or overnight delivery service, a written report of the inspection, which shall include a list of any observed deviations from the Decree, the Act, and its implementing regulations, including, but not limited to, the cGMP requirements for food;

I. Defendants notify FDA and the Sanitation and Food Safety Expert(s) in writing of the actions they have taken to correct each and all deviations listed in the Sanitation and Food Safety Expert(s)' report, if any;

J. The Sanitation and Food Safety Expert(s) certify to FDA in writing that, based upon the Sanitation and Food Safety Expert(s)' inspection and Defendants' response(s), if any, as described in paragraph 5(G) and 5(I), the facility and Defendants' methods and controls used to receive, prepare, process, manufacture, pack, hold, and distribute articles of food appear to be in compliance with this Decree, the Act, and its implementing regulations, including, but not limited to, the cGMP requirements for food;

K. Defendants retain, at their expense, an independent person or persons (the "Labeling Expert") who is without any personal or financial ties (other than the retention agreement) to Defendants or their families or operations, except that the Labeling Expert may be the same person(s) as the Sanitation and Food Safety Expert(s), and who, by reason of background, education, training, or experience, is qualified to determine whether Defendants' products are labeled in compliance with the Act and its implementing regulations, including, but not limited to, the food labeling requirements, see 21 C.F.R. Part 101, and:

i. Defendants notify FDA in writing of the name(s) and qualifications of the Labeling Expert as soon as such expert is retained;

ii. The Labeling Expert performs a review of each and all of Defendants' products' labeling to determine whether each product's labeling complies with the Act and its implementing regulations, including, but not limited to, the food labeling requirements, see 21 C.F.R. Part 101;

iii. Within twenty (20) business days after the review described in paragraph 5(K)(ii) is completed, the Labeling Expert prepares and submits contemporaneously to FDA and Defendants, by courier service or overnight delivery service, a written report of the review, which shall include a list of observed deviations, if any, from compliance with the Act and its implementing regulations, including, but not limited to, the food labeling requirements, see 21 C.F.R. Part 101;

iv. Defendants notify FDA and the Labeling Expert in writing of the actions they have taken to correct all deviations listed in the Labeling Expert's report, if any;

v. The Labeling Expert certifies to FDA in writing that all of Defendants' products' labeling complies with the Act, and its implementing regulations, including, but not limited to, the food labeling requirements, see 21 C.F.R. Part 101, taking into account any applicable regulatory exemptions that Defendants demonstrate to FDA's satisfaction that they meet;

vi. Defendants submit to FDA true and complete copies of any and all product labeling and FDA reviews such labeling to evaluate Defendants' compliance with the Act and its implementing regulations, taking into account any applicable regulatory exemptions that Defendants demonstrate to FDA's satisfaction that they meet; and

vii. Defendants receive written notification from FDA that their products' labeling appears to be in compliance with the Act and its implementing regulations, taking into account any applicable regulatory exemptions that Defendants demonstrate to FDA's satisfaction that they meet. FDA shall endeavor to provide Defendants with such written notification, as appropriate, in a timely manner;

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

M. FDA notifies Defendants, in writing, that Defendants appear to be in compliance with all the requirements specified in paragraph 5, the Act, and 21 C.F.R. Part 110. FDA shall endeavor to complete its review of Defendants' compliance with such requirements and provide such written notification, as appropriate, in a timely manner. In no circumstances shall FDA's silence be construed as a substitute for written notification.

6. Within ten (10) business days after entry of this Decree, Defendants shall, at their expense, under FDA's supervision, and pursuant to a method approved in advance by FDA in writing, destroy all in-process and finished articles of food in Defendants' possession, custody, and/or control. Defendants shall reimburse FDA for supervising the destruction at the rates set forth in paragraph 10 of this Decree. Notwithstanding the requirements of this paragraph and paragraph 5 of this Decree, Defendants shall be permitted to receive and hold articles of food supplied by one or more third persons or entities ("suppliers") at the Furneaux Road Facility, so long as such articles have never been received or held at any other facility owned or leased by Defendants, including, but not limited to, the facility located at 2451 26th Ave #1, Sacramento, California 95822-2269, and so long as:

A. The suppliers are not directly or indirectly owned, controlled, or operated by Defendants, and the suppliers are without personal or financial ties (other than the supplier distribution agreements or contracts between the parties) to Defendants or their immediate families;

B. Defendants' receiving and holding of articles of food at the Furneaux Road Facility remains at all times in compliance with the Act and its implementing regulations, including 21 C.F.R. Part 110;

C. Defendants do not perform food preparing, processing, manufacturing, labeling, packing, or distributing at or from the Furneaux Road Facility until they receive written notice from FDA that Defendants appear to be in compliance with all the requirements specified in paragraph 5, the Act, and 21 C.F.R. Part 110;

D. FDA, as and when it deems necessary, inspects the Furneaux Road Facility, including the buildings, equipment, utensils, articles of food, and all relevant records contained therein, to evaluate Defendants' compliance with this paragraph, the Act, and its implementing regulations; and

E. Should FDA determine that Defendants are not in compliance with this paragraph, the Act, and/or its implementing regulations, Defendants shall, upon written notification from FDA, take any corrective actions that FDA deems necessary and appropriate, including, but not limited to, ordering Defendants to cease receiving and holding articles of food at the Furneaux Road Facility, to destroy such articles of food, and/or to pay liquidated damages pursuant to paragraph 18 of this Decree.

7. Within thirty (30) business days after receiving the written authorization described in paragraph 5(M), Defendants shall retain at their expense, an independent person or persons (the "Auditor") who is without any personal or financial ties (other than the retention agreement) to Defendants or their families, except that the Auditor may be the same person(s) as the Sanitation and Food Safety Expert and/or the Labeling Expert, and who, by reason of background, education, training, or experience, is qualified to determine whether the facility and Defendants' methods and controls used to receive, prepare, process, manufacture, label, pack, hold, and distribute articles of food comply with the Act and its implementing regulations, including, but not limited to, sanitation, cGMP, and food labeling requirements. See, e.g., 21 C.F.R. Parts 101 (food labeling), 110 (cGMP). Thereafter:

A. Defendants shall notify FDA in writing of the name(s) and qualifications of the Auditor as soon as they retain such auditor;

B. The Auditor shall conduct audit inspections of the facility and determine whether the facility and Defendants' methods and controls used to receive, prepare, process, manufacture, label, pack, hold, and distribute articles of food comply with the Act and its implementing regulations, including, but not limited to, sanitation and cGMP requirements at least once every six (6) months, for a period of no less than two (2) years, and then at least once every year thereafter unless FDA notifies Defendants in writing that more or less frequent inspections are required;

C. Within five (5) business days after the start of the audit inspection, Defendants shall submit concurrently to the Auditor and FDA true and complete copies of the labeling for each and all of Defendants' products;

D. The Auditor shall review all such labeling to determine whether each product's labeling complies with the Act and its implementing regulations, including, but not limited to, the food labeling requirements;

E. At the conclusion of each audit inspection, the Auditor shall prepare a detailed written report ("Audit Report") analyzing whether Defendants are in compliance with this Decree, the Act, and its implementing regulations and identifying any deviations ("Audit Report Observations"). As part of every Audit Report, except the first Audit Report, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA, by courier service or overnight delivery service, no later than ten (10) business days after the date the audit inspection(s) is completed. In addition, Defendants shall maintain the Audit Reports in separate files at their facility and shall promptly make the Audit Reports available to FDA upon request;

F. If an Audit Report contains any Audit Report Observations indicating that Defendants are not in compliance with this Decree, the Act, and/or its implementing regulations, Defendants shall, within fifteen (15) business days after receipt of the Audit Report, make all necessary corrections, unless FDA notifies Defendant in writing that a shorter time frame is required. If, after receiving the Audit Report, Defendants believe that a correction of the deviations will take longer than fifteen (15) business days, Defendants shall, within five (5) business days after receiving the Audit Report, submit to FDA in writing a proposed schedule for completing corrections ("Correction Schedule"). The Correction Schedule must be reviewed and approved by FDA in writing prior to implementation by Defendants. FDA shall endeavor to complete its review of the Correction Schedule and approve, as appropriate, the Correction Schedule in a timely manner. In no circumstance shall FDA's silence be construed as a substitute for written approval; and

G. Within twenty (20) business days after Defendants receive the Audit Report or within the time frame provided in the Correction Schedule approved by FDA, the Auditor shall review each and all corrective action(s) taken by Defendants. Within five (5) business days after beginning that review, the Auditor shall report in writing to FDA whether each of the Audit Report Observations has been corrected, and, if not, which Audit Report Observations remain uncorrected.

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;

B. Violates 21 U.S.C. § 331(k), by causing articles of food within the meaning of 21 U.S.C. § 321(f) to become misbranded within the meaning of 21 U.S.C. § 343 while such articles are held for sale after shipment of one or more of their components in interstate commerce; and/or

C. 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 make inspections of Defendants' operations and facility, including, but not limited to, the facility located at 2451 26th Ave #1, Sacramento, California 95822-2269 and the Furneaux Road Facility, and any other locations at or from which Defendants receive, prepare, process, manufacture, label, pack, 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, 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 of 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: $90.65 per hour and fraction thereof per representative for inspection or investigative work; $108.63 per hour or fraction thereof per representative for analytical or review work; $0.54 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 two (2) business days after receiving written notification from FDA pursuant to paragraph 5(K)(vii) or after receiving written notification from FDA pursuant to paragraph 5(M), whichever is later, Defendants shall post a copy or copies of this Decree prominently in an employee common area at Defendants' facility in a language each employee understands and shall ensure that this Decree remains posted for as long as this Decree remains in effect. Within fifteen (15) business days after posting the Decree, 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 entry of this Decree, 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 entry of this Decree, 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 and 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) business days before any change in ownership, name or character of their business, including reorganization, relocation, dissolution, bankruptcy, assignment, sale resulting in the emergence of a successor business or corporation, the creation or dissolution of subsidiaries, or any other change in the corporate structure or identity of Wa Heng Dou-Fu & Soy Sauce Corporation, or any of their parents or subsidiaries, or the sale or assignment of any business assets, 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) business days prior to any assignment or change in business, and shall provide FDA with an affidavit, from a person with personal knowledge of the facts stated therein, stating the fact and manner of Defendants' compliance with this paragraph, no later than ten (10) business days after 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, in-process or finished articles of food to a qualified laboratory to determine whether they are contaminated with chemicals, toxins, microorganisms, or filth;

D. Re-implement any obligation under this Decree; and/or

E. Take any other corrective actions as FDA deems necessary to bring Defendants into compliance with this Decree, the Act, and/or 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 and written authorization from FDA to resume operations. 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 any of the provisions this Decree, the Act, and/or its implementing regulations, then Defendants shall pay to the United States of America liquidated damages the sum of one thousand dollars ($1,000) in liquidated damages for each day such violation

continues and an additional sum of five hundred dollars ($500) in liquidated damages 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 an adulterated or misbranded food in liquidated damages for each such unlawful shipment. 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, or the Court to impose, additional civil or criminal penalties to be paid by Defendants, or remedies based on conduct that may also be the basis for payment of liquidated damages pursuant to this paragraph.

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. 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, Defendants have 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.

23. If any deadline in this Decree falls on a weekend or a federal holiday, the deadline is continued to the next business day. The parties may, at any time, petition each other in writing to extend any deadline provided herein and, if the parties mutually agree in writing to extend a deadline, such extension may be granted without seeking leave of this Court.

24. 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 23rd day of June, 2016.

UNITED STATES DISTRICT JUDGE