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United States

JS-6

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

NEPTUNE MANUFACTURING, INC., a corporation, and ALEXANDER GOLDRING, PETER OYREKH, and SEMYON KRUTOVSKY, individuals,

Defendants.

No. 2:14-cv-09028-SJO-AS

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, having filed a complaint for injunctive relief against Neptune Manufacturing, Inc., a California corporation, and individuals Alexander Goldring, Peter Oyrekh, and Semyon Krutovsky (collectively, "Defendants"), and Defendants having appeared and having 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 over all parties to this action.

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

3. Defendants violate the Act, 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce articles of food, within the meaning of 21 U.S.C. § 321(f), namely fish or fishery products, that 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 may have been rendered injurious to health.

4. 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), namely

fish or fishery products, to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) while held for sale after shipment of one or more components in interstate commerce.

5. For the purposes of this Decree, the term "eviscerate" means to carefully and completely remove all internal organs, including gonads, in the body cavity of the fish, without puncturing or cutting them; "salt-cured" or "pickled" means preserved by any method using salt; "dried" means preserved by any method used to lower the amount of moisture in the fish; and "smoked" means preserved by treating the fish with salt, and subjecting it to the direct action of smoke from burning wood, sawdust, or similar material and/or imparting to it the flavor of smoke by a means such as immersing it in a solution of wood smoke.

6. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who have received actual notice of this Decree by personal service or otherwise are hereby permanently restrained and enjoined, under the provisions of 21 U.S.C. § 332(a) and the equitable authority of this Court, from directly or indirectly receiving, preparing, processing, packing, labeling, holding, and distributing articles of food, at or from their facility located at 5429 ½ W. Pico Boulevard, Los Angeles, California ("the facility"), and/or any other location(s) at or from

which Defendants, now or in the future, receive, prepare, process, pack, label, hold, or distribute articles of food, 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 Defendants' facility for the presence of *Listeria monocytogenes* ("*L. mono*") and for water phase salt levels in fish and/or fishery products, in a manner that is acceptable to the United States Food and Drug Administration ("FDA"). Defendants shall notify FDA in writing immediately upon retaining such laboratory and shall provide FDA a copy of the service contract. Such service contract shall contain provisions, acceptable to FDA, for environmental and finished product sample analyses;

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

(1) Conduct hazard analyses to develop adequate HACCP plans for Defendants' fish or fishery products, as required by 21 C.F.R. § 123.6(a)-(c);

(2) Verify and ensure the adequacy of Defendants' HACCP plans, including but not limited to: (i) conducting scientific validation studies of the adequacy of the critical limits

listed in Defendants' HACCP plans for fish that are not eviscerated at the time of receipt, which include but are not limited to Defendants' cold-smoked herring, cold smoked mackerel, hot smoked mackerel, and pickled herring; and (ii) ensuring that large fish (i.e., those more than five (5) inches in length) used in the production of smoked, dried, or salt-cured (pickled) finished products are eviscerated before being salted or submerged in a salt solution;

(3) Develop procedures for processing Defendants' fish or fishery products to achieve water phase salt levels that adequately control *Clostridium botulinum* ("*C. bot*") for all of Defendants' fish or fishery products;

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

(5) Develop a Listeria Monitoring Program in accordance with paragraph (C)(6) below;

(6) Collect product and environmental samples from within Defendants' facility for water phase salt level testing and for pathogen testing in accordance with paragraph (C) below;

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

(8) Develop and conduct employee training programs (in English and any other language necessary to convey the substance

of the training) on the SSOPs, seafood HACCP and cGMP requirements, and Listeria Monitoring Program; and

(9) Inspect Defendants' facility and determine whether the methods, facilities, and controls are operated and administered in conformity with the Act, its implementing regulations, and this Decree;

Defendants shall notify FDA in writing of the name(s) and qualifications of the Expert(s) under paragraph (B) as soon as they retain such Expert(s).

(C) After review of all FDA inspectional observations of deficiencies from August 2006 to the present, and after consultation with the Laboratory, Defendants' Expert(s), in conjunction with Defendants:

(1) Develops, to FDA's satisfaction, adequate written HACCP plan(s), as required by 21 C.F.R. Part 123, for each type of fish and/or fishery products received, prepared, processed, packed, labeled, held, and/or distributed by Defendants, that at a minimum:

(a) ensures that large fish (more than five inches in length) used in Defendants' production of smoked, dried, or salt-cured (pickled) finished products are eviscerated before being salted or submerged in a salt solution (e.g., thawing);

(b) ensures that each brining tank of in-process fish or fishery products is prepared and monitored in such a

manner that the fish contained therein have adequate, uniform, and consistent water phase salt levels at this processing step; and

(c) effectively controls food safety hazards, including but not limited to: (i) those associated with *C. bot* growth and toxin formation likely to occur in smoked, dried, or salt-cured (pickled) fish and fishery products under normal and moderate temperature abuse conditions; and (ii) those associated with histamine formation;

(2) Develops and conducts, to FDA's satisfaction, scientific validation studies of the adequacy of the critical limits listed in Defendants' HACCP plans for fish that are not eviscerated prior to receipt by Defendants and, based on the results of such validation studies, revises the HACCP plans accordingly;

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

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

(5) Develops, 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 shall ensure that Defendants' operations comply with the Act and 21 C.F.R. Part 110;

(6) Develops and implements, to FDA's satisfaction, a written Listeria Monitoring Program that shall include, at a minimum, the following:

(a) 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);

(b) an effective program for environmental monitoring and testing of Defendants' facility to ensure that such pathogenic organisms as *Listeria species* ("*L. spp.*") are systemically controlled and that *L. mono* does not occur in finished products. Sampling shall 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 paragraph (C)(6)(b) are sent to FDA within two (2) calendar days after receipt by Defendants; and

(c) an adequate written plan for remedial action that Defendants shall implement should *L. spp.*, *L. mono*, or any other pathogenic organism be detected. The remedial action plan

shall include intensified sanitation and intensified sampling measures that are acceptable to FDA.

(7) Develops and conducts, to FDA's satisfaction, employee training programs (in English and any other language necessary to convey the substance of the training) on the seafood HACCP and cGMP regulations; HACCP plans; SSOPs; 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 performs duties at the facility for Defendants have received such training; and

(8) Submits to FDA the written HACCP plans and all associated records (including monitoring records), validation studies, SSOPs, Listeria Monitoring Program, and training programs developed pursuant to paragraph (C)(1)-(7) above; and documentation demonstrating that the Expert(s) has trained Defendants and each of their officers, employees, and any other person(s) who performs duties at the facility for Defendants, as described in paragraph (C)(7) above;

(D) Defendants assign continuing responsibility for the operation of the Listeria Monitoring Program discussed in paragraph (C)(6) above to a person (or persons), who, by reason of background, experience, or education, is qualified to maintain Defendants' facility in a sanitary condition, coordinate with the Laboratory,

and implement any necessary remedial action(s), and provide such person(s) with the authority to achieve the necessary corrections;

(E) Defendants make the Listeria Monitoring Program available and accessible to all their officers, employees, and any other person(s) who performs duties at the facility for Defendants in English and any other language necessary to convey the substance of such program;

(F) FDA has approved, in writing, the seafood HACCP plan(s), validation studies, SSOPs, Listeria Monitoring Program, and training programs and documentation developed by the Expert(s), as specified in paragraphs (C)(1)-(7) above;

(G) Defendants successfully complete the training program approved by FDA pursuant to paragraph (F) above;

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

(I) 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 foods to determine whether Defendants are operating in compliance with this

Decree, the Act, and all applicable regulations. The Expert(s) shall verify, with supporting documentation, that: (i) Defendants have corrected all of the seafood HACCP and cGMP deficiencies observed by FDA since August 2006, specifying each FDA observation and Defendants' corrections thereof; (ii) the monitoring equipment used to implement Defendants' HACCP plans is suitable and performing adequately; and (iii) Defendants' facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute foods are, in the Expert's opinion, in compliance with this Decree, the Act, and its implementing regulations. The Expert(s) shall submit, in writing, all findings and supporting documentation to Defendants and FDA concurrently, within fifteen (15) calendar days after completion of the inspection;

(J) Defendants destroy, under FDA's supervision, and according to a destruction plan submitted in writing by Defendants and approved in writing by FDA prior to implementation, all smoked, dried, and salt-cured (pickled) fish or fishery products in their custody, control, or possession at the time this Decree is signed by the parties;

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

(L) Defendants have paid all costs of inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to paragraphs (A) through (M), at the rates set forth in paragraph 14 below; and

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

7. Defendants shall notify FDA in writing of their intent to process any smoked, dried, or pickled fish or fishery product(s) for which Defendants do not have a HACCP plan approved by FDA pursuant to paragraph 6(F) above. Defendants shall not receive, prepare, process, pack, hold, label, or distribute such product(s) until a written HACCP plan(s) for that product is submitted to and approved by FDA in writing.

8. Immediately upon resuming operations after completing the requirements of paragraph 6, Defendants shall, in consultation with the Expert(s), continuously implement the written HACCP plans, SSOPs, and Listeria Monitoring Program approved by FDA pursuant to paragraph 6(F). Defendants further shall comply with the following requirements:

(A) Defendants shall conduct finished product testing for water phase salt level in the following manner:

(1) Defendants shall have tested a randomly collected, representative sample from every lot of finished fish or

fishery products that they process for the first fifteen (15) consecutive production days, and all such samples shall have a water phase salt level that adheres to the critical limits set forth in the HACCP plans approved by FDA pursuant to paragraph 6(F);

(2) After satisfying the requirements of paragraph (A)(1), 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;

(3) After satisfying the requirements of paragraph (A)(2), Defendants shall have tested a randomly collected, representative sample from one lot of each type of finished fish or fishery products they process each month for the next twelve (12) months; and

(4) After satisfying the requirements of paragraph (A)(3), Defendants shall have tested a randomly collected, representative sample from one lot of each type of finished fish or fishery products they process every three (3) months thereafter.

Defendants shall send copies of the results of tests conducted pursuant to paragraph (A) to FDA within two (2) calendar days after receipt by Defendants. If any sample analysis conducted pursuant to paragraph (A) shows a water phase salt level that does not adhere to the critical limits set forth in the HACCP plans approved by FDA pursuant to paragraph 6(F), Defendants shall immediately destroy the affected lot(s) at Defendants' expense, under FDA's supervision, and

pursuant to a destruction plan approved in writing by FDA. Defendants further shall reassess their processing operations to determine the cause of the deviation, correct the deviation, revise their HACCP plan(s) accordingly, and submit such revisions for FDA's written approval. After correcting the cause of the deviation, Defendants shall reinstate the complete sequence of testing under paragraph (A) anew; and

(B) Defendants shall conduct finished product testing for *L. mono* in the following manner:

(1) Defendants shall have tested for *L. mono* in a randomly collected, representative sample from every lot of fish or fishery products that they process for the first fifteen (15) consecutive production days;

(2) After the completion of testing under paragraph (B)(1), 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;

(3) After the completion of testing under paragraph (B)(2), 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

(4) After the completion of testing under paragraph (B)(3), 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.

Defendants may use the same fish or fishery products that they sampled for water phase salt level testing in accordance with paragraph (A) for the purpose of *L. mono* testing pursuant to paragraph (B). Defendants shall send copies of the results of all testing conducted pursuant to paragraph (B) to FDA within two (2) calendar days after receipt by Defendants. If any laboratory test completed pursuant to paragraph (B) shows the presence of *L. mono* in any article of food, then Defendants must immediately cease production and notify FDA that production has ceased. Defendants shall also 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* were collected. Defendants may resume production only when they have determined and corrected the cause of the contamination and only after FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements of this Decree, the Act, and all applicable regulations. After correcting the cause of the contamination, Defendants shall reinstate the complete sequence of testing under paragraph (B) anew;

(C) In the event that Defendants or their Expert(s) determine that the Listeria Monitoring Program that FDA approved

pursuant to paragraph 6(F) 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. The alternative *L. mono* control program submitted to FDA shall consist of methods and controls that are shown to FDA's satisfaction to systemically control pathogenic organisms such as *Listeria species* ("*L. spp.*") and ensure that *L. mono* does not occur in finished products.

9. If, after notifying FDA of the name of the laboratory retained to conduct sample collection and analyses pursuant to paragraph 6(A), Defendants terminate or in any way alter their service contract with the laboratory, Defendants shall notify FDA within seven (7) calendar days. 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 of execution.

10. Within thirty (30) calendar days after Defendants resume their operations after completing the requirements of paragraph 6, the Expert(s) shall conduct a comprehensive inspection of the facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute foods to determine whether Defendants are operating in compliance with this Decree, the Act, and all applicable regulations. The Expert(s) shall submit 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 then 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 6, 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 Defendants' facility and the methods and controls Defendants use to receive, prepare, process, pack, label, hold, and distribute articles of food are in compliance with the requirements of this Decree, the Act, and all applicable regulations, and shall certify compliance in the Expert's report.

11. Defendants and each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) who receive actual notice of 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 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. § 321(f) that is adulterated 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 of their components in interstate commerce; and/or

(C) Results in the failure to implement and continuously maintain the requirements of this Decree.

12. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendants' facility, and any other locations at which Defendants receive, prepare, process, pack, label, 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 Decree, the Act, and its implementing regulations. During the inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein; to take photographs and make video recordings; to take samples of Defendants' raw ingredients, in-process, and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, preparing, processing, packing, holding, labeling, and distributing any and all articles of food. The inspections shall be permitted upon presentation of a copy of

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

13. Defendants shall notify FDA in writing at least fifteen (15) calendar days before any change in ownership, name or character of their business, including reorganization, relocation, dissolution, assignment, or lease or sale of the business or any assets of the business, such as buildings, equipment, or inventory, that may affect compliance with the obligations arising from this Decree. Defendants shall provide any prospective successor or assign with a copy of this Decree at least ten (10) calendar days before the assignment or change in business, and shall provide FDA with an affidavit of compliance with this paragraph within ten (10) calendar days of providing a copy of this Decree to a prospective successor or assign.

14. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, at the standard rates prevailing at the time costs are incurred, and Defendants shall make payment in full to FDA within (30) calendar days of receiving written notification from FDA of the costs. As of the date that this Decree is signed by the parties, these rates are: $88.45 per hour and fraction thereof per representative inspection work; $106.03 per hour or fraction thereof per representative analytical or review work; $0.56 per mile for

travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

15. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample, report submitted by the Expert(s), 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, packing, labeling, holding, and 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 additional samples to a qualified laboratory for analysis;

(D) Assess liquidated damages, as provided by paragraph 18 of this Decree;

(E) Institute or re-implement any of the requirements set forth in this Decree; and

(F) Take any other corrective actions as FDA deems necessary to protect the public health or 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, review, travel, and subsistence expenses to implement and monitor recalls and other actions, at the rates specified in paragraph 14 of this Decree.

16. Upon receipt of any order issued by FDA pursuant to paragraph 15, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in paragraph 15 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 the Decree, the Act, and its implementing regulations, and that Defendants may 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.

17. Defendants shall maintain copies of their HACCP plans, along with copies of all records required by such plans, 21 C.F.R. Part 123, or this Decree, at their facility in a location where they are readily available for reference and inspection by FDA. All records required to be kept by Defendants' HACCP plans, FDA regulations, and this Decree shall be retained for at least three (3) years after the date the records are prepared and shall be presented immediately to FDA investigators upon request.

18. If any Defendant fails to comply with the provisions of the Act, its implementing regulations, and/or this Decree, then Defendants shall pay to the United States of America liquidated damages in the sum of one thousand five hundred dollars ($1,500) for each day that such violation continues; an additional sum of one thousand dollars ($1,000) in liquidated damages per day for each violation of the Act, its implementing regulations, and/or this Decree (e.g., if two violations occur for two days, the liquidated damages shall be $7,000); and an additional sum equal to twice the retail value of each shipment of food that is adulterated or otherwise in violation of the Act, its implementing regulations, or this Decree. 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 liquidated damages pursuant to this paragraph.

19. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, then Defendants shall, in addition to other remedies, reimburse the United States 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 and shall be final. If contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before the FDA at the time the decision was made. No discovery shall be taken by either party.

21. Within ten (10) calendar days after entry of this Decree, Defendants shall provide a copy of this Decree by personal service or certified mail (return receipt requested) to each and all of their officers, agents, employees, representatives, successors, assigns, attorneys, and any and all persons in active concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships). Defendants shall provide to FDA within thirty (30) calendar days of

the date of the entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified and attaching copies of the executed certified mail return receipts or other proof of service if the Decree was delivered by personal service.

22. Defendants shall prominently post a copy of this Decree (in English and any other language necessary to convey the substance of the Decree) in an employee common area at Defendants' facility within ten (10) calendar days of the entry of this Decree and shall ensure that the Decree remains posted for as long as the Decree remains in effect.

23. Defendants shall, within ten (10) calendar days of the entry of this Decree, hold a general meeting or a series of smaller meetings for employees of the facility, at which they shall describe the terms and obligations of this Decree (in English and any other language necessary to convey the substance of the Decree). Defendants shall provide to FDA within thirty (30) calendar days of the entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all meeting attendees and attaching a copy of the meeting sign-in sheet(s).

24. In the event that any Defendant becomes associated with any additional officers, agents, employees, representatives, successors, assigns, attorneys, or any additional persons in active

concert or participation with any of them (including individuals, directors, corporations, subsidiaries, affiliates, and partnerships) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (return receipt requested), to such persons. Within ten (10) calendar days of each instance that any Defendant becomes associated with any such person, Defendants shall provide to FDA an affidavit stating the fact and manner of Defendants' compliance with this paragraph, identifying the names, addresses, and positions of all persons who received a copy of this Decree pursuant to this paragraph, and attaching a copy of the executed certified mail return receipts.

25. Defendants shall address all communications required under this Decree to the Director, Los Angeles District Office, Food and Drug Administration, 19701 Fairchild, Irvine, CA 92612 and shall reference this civil action by case name and civil action number and shall prominently mark "Decree Correspondence" in such communication.

26. 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 or appropriate.

SO ORDERED:

Dated this 1st day of December, 2014.

S. James Otero

_____

UNITED STATES DISTRICT JUDGE

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