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JS-6

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

MICHEL G. BLANCHET,

Defendant.

2:17-cv-07273-RGK-AS

No. ~~2:17-cv-27273-RGK(AS~~)

[~~PROPOSED~~] CONSENT DECREE OF PERMANENT INJUNCTION

Before the Honorable R. Gary Klausner, United States District Judge

Plaintiff, the United States of America (the "United States"), by its undersigned attorneys, having filed a complaint for injunctive relief (the "Complaint") against Michel G. Blanchet ("Defendant"), and Defendant having appeared, filed an answer, and consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest and before any testimony has been taken, and solely for the purposes of settlement, and the United States 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 Defendant under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* (the "Act").

3. The Complaint alleges that Defendant violates the Act, 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce 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. The Complaint alleges that Defendant violates 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 of its components in interstate commerce.

5. Defendant represents that, as of the date of the entry of this Decree, he is not engaged in, either directly or indirectly, receiving, preparing, processing, packing, labeling, holding, and/or distributing fish or fishery products, nor is he causing the receipt, preparation, processing, packing, labeling, holding, and/or distribution of any fish or fishery products.

6. "Defendant's Facility" is defined as any commercial location(s) at or from which Defendant, now or in the future, directly or indirectly receives, prepares, processes, packs, labels, holds, and/or distributes fish or fishery products.

7. If Defendant intends to resume, either directly or indirectly, receiving, preparing, processing, packing, labeling, holding, and/or distributing fish or fishery products at or from Defendant's Facility, or causing any such activities at or from Defendant's Facility, he shall notify FDA in writing in advance of resuming any such activities. This notice shall identify the type(s) of fish or fishery products Defendant

intends to receive, prepare, process, pack, label, hold, and/or distribute and his roles and responsibilities in such activities. In addition, if Defendant intends to resume, either directly or indirectly, receiving, preparing, processing, packing, labeling, holding, and/or distributing articles of fish or fishery products at or from Defendant's Facility, Defendant shall not resume any such activities until Defendant has complied with Paragraph 8(A)-(G) of this Decree, FDA has inspected Defendant's Facility pursuant to Paragraph 8(H) of this Decree, Defendant has paid the costs of such inspection(s) pursuant to Paragraph 8(I) of this Decree, and Defendant has received written notice from FDA, as required by Paragraph 8(J) of this Decree, and shall resume such activities only to the extent authorized in FDA's written notice.

8. Upon entry of this Decree, Defendant and each and all of his 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 received actual notice of this Decree by personal service or otherwise is hereby permanently restrained and enjoined, under the provisions of 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 fish or fishery products, at or from Defendant's Facility, unless and until:

A. Defendant retains, at his expense, an independent person or persons (the "Expert" or "Experts") having no personal or financial ties (other than the retention agreement) to Defendant or his family, and who, by reason of background, education, training, and experience, is qualified to assist Defendant in complying with the seafood Hazard Analysis Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123. The Expert's seafood HACCP qualifications shall include, but not be limited to: developing procedures to adequately control for the risk of Listeria monocytogenes ("*L. mono*") and C. botulinum ("*C. bot.*") toxin formation in Defendants' seafood; developing adequate written Standard Sanitation Operating Procedures ("SSOPs"), as required by 21 C.F.R. §

123.11; establishing a Pathogen Control Program, pursuant to Paragraph 8(B)(4), for the genus Listeria ("*L. spp.*"); and developing and conducting employee training programs on sanitation and pathogen controls, and on complying with this Decree, the Act, and 21 C.F.R. Part 123. Defendant shall notify FDA in writing of the name(s) and qualifications of the Expert(s) under Paragraph 8(A) within five (5) calendar days of retaining such expert;

B. The Expert(s), in conjunction with Defendant:

(1) Conducts hazard analyses for each type of fish and fishery product Defendant intends to process to identify all food safety hazards reasonably likely to occur, in accordance with 21 C.F.R. § 123.6(a);

(2) Develops and submits to FDA adequate written seafood HACCP plans, as explained in 21 C.F.R. Part 123, which include, for each food safety hazard reasonably likely to occur in each of Defendant's seafood products, critical control points, critical limits, and written corrective action plans addressing deviations from critical limits. Defendant's seafood HACCP plans must effectively control for all food safety hazards reasonably likely to occur for each type of fish and fishery product that Defendant intends to process, including, but not limited to, *C. bot.* toxin formation in smoked fish and fishery products;

(3) Provides evidence of the adequacy of the critical limits listed in Defendant's seafood HACCP plans to control for all food safety hazards reasonably likely to occur for each type of fish and fishery product that Defendant intends to process, including, but not limited to, *C. bot.* toxin formation in smoked fish and fishery products;

(4) Develops and submits to FDA adequate written SSOPs, as required by 21 C.F.R. § 123.11, that, at a minimum, ensure on an ongoing basis that Defendant's Facility and all equipment contained therein are clean, sanitized, and suitable for receiving, preparing, processing, packing, holding, and distributing fish or fishery products, and that Defendant's operations comply with the Act and its

implementing regulations;

(5) Develops and submits to FDA an effective program ("Pathogen Control Program") for monitoring and testing, at appropriate frequencies, food-contact surfaces, equipment, and other environmental sites where fish is received, prepared, processed, packed, held, and distributed, up to and including final packaging, and common areas that could be reservoirs for cross-contamination, to ensure that *L. spp.* is controlled within Defendant's Facility and that *L. mono* does not occur in the finished product. Environmental testing shall be performed, in accordance with timetables submitted to and approved in writing by FDA before testing begins, by a qualified, independent laboratory having no personal or financial ties (other than the retention agreement) to Defendant or his family ("the Laboratory"), identified in the Pathogen Control Program. Defendant shall ensure that the Laboratory will perform its analysis in a manner acceptable to FDA. Defendant shall ensure that all of the independent laboratory's test results are provided to FDA within two (2) calendar days after receipt by Defendant. The Pathogen Control Program must include a plan for remedial action should *L. spp.* be detected; and

(6) Develops and submits to FDA employee training programs on Defendant's seafood HACCP plans, the SSOPs, and the Pathogen Control Program;

C. FDA has approved, in writing, the seafood HACCP plan(s), SSOPs, Pathogen Control Program, and employee training programs developed by the Expert(s), as specified in Paragraphs 8(B)(1)-(6);

D. Defendant successfully implements the employee training programs developed by the Expert(s) and approved by FDA according to Paragraph 8(C);

E. Defendant, at his expense, cleans and sanitizes Defendant's Facility and equipment and makes improvements, thereby rendering Defendant's Facility and equipment suitable for receiving, preparing, processing, packing, holding, and distributing fish or fishery products, and Defendant ensures that Defendant's Facility and equipment will be continuously maintained in a sanitary condition;

F. Defendant reports to FDA, in writing, the actions he has taken to bring his operations into compliance with this Decree, the Act, and all applicable regulations, including the specific measures Defendant has taken to address each of the deficiencies documented by FDA since January 2016;

G. The Expert(s) conduct a comprehensive inspection of Defendant's Facility and the methods and controls used to receive, prepare, process, pack, hold, and distribute fish or fishery products to determine whether Defendant's Facility is sanitary and Defendant is fully prepared to operate in compliance with this Decree, the Act, and all applicable regulations. The Expert(s) shall submit all findings, in writing, to Defendant and FDA concurrently, within ten (10) business days of completion of the inspection;

H. FDA, if and when it deems necessary to evaluate Defendant's compliance with the terms of this Decree, the Act, and all applicable regulations, has inspected Defendant's Facility, including the building, sanitation-related systems, equipment, utensils, articles of food, and relevant records contained therein;

I. Defendant pays all costs of inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to Paragraphs 8(A) through 8(H), at the rates set forth in Paragraph 17 below; and

J. FDA notifies Defendant in writing that Defendant appears to be in compliance with the requirements set forth in Paragraphs 8(A) through 8(I) of this Decree, the Act, and its implementing regulations.

9. Within thirty (30) calendar days after entry of this Decree, Defendant shall destroy, under FDA's supervision and pursuant to a destruction plan approved in writing by FDA, all fish and fishery products in Defendant's custody, control, and/or possession, as of the date this Decree is signed by both parties.

10. If Defendant elects to resume operations, after completing the requirements of Paragraph 8, Defendant shall, in consultation with the Expert(s) and outside Laboratory:

A. Continuously implement the FDA-approved seafood HACCP plans, SSOPs, and Pathogen Control Program. In the event that Defendant or his Expert(s) determines that the FDA-approved Pathogen Control Program needs to be revised, Defendant shall provide proposed changes to FDA in writing at least twenty (20) calendar days prior to their implementation, and shall not implement his proposed changes until FDA approves those changes in writing. Any alternative Pathogen Control Program submitted to FDA shall consist of methods and controls that are shown to FDA's satisfaction to systemically control organisms such as *L. spp.* and ensure that *L. mono* does not occur in finished products;

B. Have a randomly-collected, representative sample from every lot of vacuum-packaged, smoked fish product processed from the first production batch of each different type of vacuum-packaged, smoked fishery product tested to ensure that Defendant adheres to the critical limits set forth in the seafood HACCP plan(s) approved by FDA in Paragraph 8(C). If Defendant deviates from the critical limits, he must take corrective actions as specified in his approved seafood HACCP plan(s) under FDA's supervision, and repeat the testing specified in this Subparagraph until all representative samples comport with the critical limits;

C. In addition to the first batch testing requirement in Subparagraph (B) of this Paragraph, have a randomly-collected, representative sample from one lot of each type of vacuum-packaged, smoked fishery product that he processes for each month in the first three (3) months tested to ensure that Defendant adheres to the critical limits set forth in the seafood HACCP plan approved by FDA in Paragraph 8(C). If Defendant has any deviations from the critical limits, he must take corrective actions as specified in his approved seafood HACCP plan and under FDA's supervision, and repeat the testing specified in this Subparagraph until all representative samples comport with the critical limits; and

D. Defendant shall send copies of the results of tests conducted pursuant to Subparagraphs (B)-(C) of this Paragraph to FDA within two (2) calendar days after receipt by Defendant.

11. If, after notifying FDA of the name of the Laboratory retained to conduct sample collection and analyses in the Pathogen Control Program, Defendant terminates or in any way alters his service contract with the Laboratory, Defendant shall notify FDA within seven (7) calendar days. If Defendant terminates his service contract, Defendant shall provide a copy of the service contract with the new Laboratory to FDA within five (5) business days of execution. At all times while this Decree is in effect, Defendant shall have in place a service agreement with a laboratory to institute the testing required by Pathogen Control Program.

12. After receiving notice from FDA pursuant to Paragraph 8(J), Defendant shall not import, receive, prepare, process, pack, hold, label, or distribute any fish or fishery product not identified in a written seafood HACCP plan approved by FDA until Defendant submits for FDA's review a written seafood HACCP plan for such fish or fishery product and receives FDA's written approval. In no circumstances shall FDA's silence be construed as a substitute for written approval.

13. If Defendant elects to resume operations, within thirty (30) calendar days after receiving FDA's notification under Paragraph 8(J), the Expert(s) shall conduct a comprehensive inspection of Defendant's Facility and the methods and controls used to receive, prepare, process, pack, label, hold, and distribute fish or fishery products to determine whether Defendant is operating in compliance with this Decree, the Act, and all applicable regulations. The Expert(s) shall submit a report documenting all findings to Defendant and FDA concurrently, within ten (10) calendar days after completing the inspection. Thereafter, the Expert(s) shall conduct quarterly audits of Defendant's Facility for one year, and then one audit every six (6) months for the next two (2) years. Beginning in the fourth year after Defendant resumes operations after completing the requirements of Paragraph 8, the Expert(s) shall conduct inspections of Defendant's

Facility annually unless FDA informs Defendant in writing that more frequent expert inspections and reporting are required.

A. During each inspection of Defendant's Facility conducted by the Expert(s), the Expert(s) shall verify that Defendant's Facility and the methods and controls Defendant uses to receive, prepare, process, pack, label, hold, and distribute fish or fishery products are in compliance with the requirements of this Decree, the Act, and its implementing regulations, and shall certify such in the Expert's report submitted to Defendant and FDA concurrently as described in this Paragraph.

B. If the Audit Report contains any observations indicating that Defendant is not in compliance with this Decree, the Act, or its implementing regulations, Defendant shall, within fifteen (15) business days after receipt of the Expert's report, make all necessary corrections, unless FDA notifies Defendant in writing that a shorter timeframe is required or that a longer timeframe is appropriate.

14. Defendant, and each and all of his 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 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 to become adulterated under 21 U.S.C. § 342(a)(4) while such article is held for sale after shipment of one or more of its components in interstate commerce; or

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

15. FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of Defendant's Facility 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; to take photographs and make video recordings; to take samples of Defendant's in-process and finished articles of food, containers, and packaging material; and to examine and copy all records related to receiving, processing, manufacturing, preparing, packing, holding, and/or 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.

16. If Defendant elects to resume operations, Defendant 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. Defendant 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.

17. Defendant shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendant's compliance with this Decree, at the standard rates prevailing at the time costs are incurred, and Defendant 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 (i) $93.26 per hour and fraction thereof per representative inspection work, (ii) $111.77 per hour or fraction thereof per representative analytical or review work, (iii) $0.535 per mile for travel by automobile, (iv) the government rate or the equivalent for travel by air or other means, and (v) 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 for FDA supervision of Court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

18. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, audit, analysis of a sample, report submitted by the Expert(s), or other information, that Defendant has failed to comply with any provision of this Decree, has 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 Defendant in writing and order Defendant to take appropriate action, including, but not limited to, ordering Defendant immediately to take one or more of the following actions:

A. Cease receiving, preparing, processing, packing, labeling, holding, and distributing any fish or fishery products;

B. Recall all fish or fishery products that have been distributed and/or are under the custody and control of Defendant's agents, distributors, customers, or consumers;

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

D. Institute or re-implement any of the requirements set forth in this Decree; and

E. Take any other corrective actions as FDA deems necessary to protect the public health or bring Defendant into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this Paragraph shall be separate and apart from, and in addition to, all other remedies available to FDA. Defendant 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 17 of this Decree.

19. Upon receipt of any order issued by FDA pursuant to Paragraph 18, Defendant shall immediately and fully comply with the terms of the order. Any cessation of operations or other action as described in Paragraph 18 shall be implemented immediately upon notice from FDA and shall continue until Defendant receives written notification from FDA that Defendant appears to be in compliance with the Decree, the Act, and its implementing regulations, and that Defendant may resume operations. After a cessation of operations, and while determining whether Defendant is in compliance with this Decree, the Act, and its implementing regulations, FDA may require Defendant to re-institute or re-implement any of the requirements of this Decree.

20. Defendant shall maintain copies of his seafood HACCP plans, along with copies of all records required by such plans, 21 C.F.R. Part 123, and this Decree, at Defendant's Facility in a location where they are readily available for reference and inspection by FDA. All records required to be kept by Defendant's seafood 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.

21. If Defendant fails to comply with the provisions of the Act, its implementing regulations, or this Decree, then Defendant shall pay to the United States of America liquidated damages in the sum of three thousand dollars ($3,000) for each day that such violation continues; an additional sum of three thousand dollars ($3,000) in liquidated damages per day for each violation of the Act, its implementing regulations, or this Decree; and a further 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. Defendant understands and agrees 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 this 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.

22. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendant 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.

23. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. If contested, 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.

24. Within ten (10) calendar days after entry of this Decree, Defendant shall provide a copy of this Decree by personal service or certified mail (return receipt requested) to each and all of his 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). Defendant shall provide to FDA, within thirty (30) calendar days after entry of this Decree, an affidavit stating the fact and manner of compliance with this Paragraph and identifying the names and positions of all persons notified and attaching copies of the executed certified mail return receipts or other proof of service if the Decree was delivered by personal service.

25. In the event that 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, Defendant 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 after each instance that any Defendant becomes associated with any such person, Defendant shall provide to FDA an affidavit stating the fact and manner of Defendant's 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.

26. Defendant shall address all communications required under this Decree to the Program Division Director, Division of Human and Animal Food Operations West 5, U.S. Food and Drug Administration, 19701 Fairchild Road, Irvine, California 92612, and shall reference this civil action by case name and civil action number and shall prominently mark "Decree Correspondence" in all such communications.

27. 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 24th day of May, 2018.

Gary Klausner

Honorable R. Gary Klausner
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to entry of the foregoing Decree.

FOR DEFENDANT:

_____
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_____
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FOR PLAINTIFF:

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