IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MAINE

UNITED STATES OF AMERICA, Plaintiff, v. MILL STREAM CORPORATION, a corporation, doing business as SULLIVAN HARBOR FARM and IRA J. (JOEL) FRANTZMAN an individual, Defendants.	Civil No.: 1:16-cv-00080-JDL CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America (the "United States"), by its undersigned attorneys, having filed a complaint for injunctive relief (the "Complaint") against Mill Stream Corporation, a Maine corporation doing business as Sullivan Harbor Farm ("Corporate Defendant"), and individual Ira J. Frantzman (together, "Defendants"), and Defendants having appeared and having consented to entry of this Consent Decree of Permanent Injunction ("Decree") without contest, solely for the purpose of settling this case and without admitting or denying the allegations, and before any testimony has been taken, 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 over all parties to this action.

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

3. The Complaint alleges that Defendants receive raw fish and prepare, process, pack, hold, and distribute refrigerated, vacuum packed, ready-to-eat cold and hot smoked fish or fishery products in interstate commerce, at and/or from their manufacturing facility, located at 1545 U.S.

Highway 1, Hancock, Maine (the "1545 Facility"). The Complaint alleges that 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. 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), 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. Defendants represent to Plaintiff and the Court that Defendant Frantzman is a co-owner of the Ironbound Restaurant and Inn, located at 1513 Highway 1, Hancock, Maine (the "Restaurant"), and that the Restaurant has sold and served to its retail customers smoked or cured fish or fishery products manufactured by the Defendants for their customers' end-point consumption. Defendants further represent that the Corporate Defendant owns and operates a retail store on or adjacent to the premises of the 1545 Facility (the "Retail Store"). The Retail Store has held, sold, and/or distributed fish or fishery products manufactured by Defendants as well as other merchandise and food products manufactured by wholly unrelated third-party suppliers.

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, including but not limited to cold and hot smoked fish or fishery products, at or from the 1545 Facility and/or any other location(s) at or from which any Defendant, now or in the future, receive, prepare, process, pack, label, hold, or distribute articles of food ("Defendants' Facility"), unless and until:

(A) Defendants retain, at their expense, an independent laboratory (the "Laboratory") having no personal or financial ties (other than the retention agreement) to Defendants or their families, and that is qualified to collect and analyze product samples collected at Defendants' Facility for water phase salt levels and environmental and product samples for the presence of *Listeria monocytogenes* ("*L. mono*") at Defendants' Facility 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;

(B) Defendants retain, at their expense, an independent expert or experts (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) develop adequate Hazard Analysis and Critical Control Point ("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, conducting scientific validation studies of the adequacy of the critical limits listed in Defendants' HACCP plans for fish or fishery products including, but are not limited to, smoked salmon, trout, and char;

(3) develop procedures for processing Defendants' fish or fishery

products to achieve water phase salt levels that adequately control *Clostridium botulinum* ("*C. bot*") hazards;

(4) develop adequate written Sanitation Standard Operating Procedures ("SSOPs") in accordance with paragraph 6(C)(3), below;

(5) develop a Listeria Monitoring Program in accordance with paragraph 6(C)(4), below;

(6) evaluate Defendants' compliance with current good manufacturing practice ("cGMP") requirements for food, as set forth under 21 C.F.R. Part 110;

(7) develop and conduct employee training programs on the seafood HACCP and cGMP regulations, and SSOPs, HACCP plans, and Listeria Monitoring Program approved by FDA pursuant to paragraph 6(E) below; and

(8) inspect Defendants' Facility and determine whether their 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 6(B) as soon as they retain such Expert(s).

(C) after review of all FDA inspectional observations of deficiencies from February 2004 to the present, Defendants' Expert(s), in conjunction with Defendants, has:

(1) developed, 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, or distributed by Defendants. Such HACCP plan(s) shall effectively control food-safety hazards reasonably likely to occur for each type of fish or fishery product that Defendants intend to process, in accordance with 21 C.F.R. Part 123, including, but not limited to, *C. bot.* growth and toxin formation in smoked fish or fishery products; and

(2) developed and conducted, to FDA's satisfaction, scientific validation studies of the adequacy of the critical limits listed in Defendants' HACCP plans for their fish and/or fishery products, and made changes to the HACCP plan(s), as necessary, based on the results of the studies. Such studies shall, at a minimum, confirm that the critical limits established for refrigerated vacuum-packaged, hot and cold smoked fish or fishery products are sufficient to consistently achieve a water phase salt level of 3.5% or higher;

(3) developed, 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)-(d), and shall ensure that Defendants' operations comply with the Act and 21 C.F.R. Part 110;

(4) developed and implemented, to FDA's satisfaction, a written Listeria Monitoring Program that shall include, at a minimum, the following:

(a) effective sanitation 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 organisms such 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.*, how, where, and when to sample; the number and frequency of samples to be collected; the methods of analyses) that are approved by FDA prior to implementation. Defendants shall ensure that the results of all analyses conducted pursuant to paragraph 6(C)(4)(b) are sent to FDA within two (2) calendar days after receipt by Defendants; and

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

(5) developed and conducted, to FDA's satisfaction, an employee training program (in English and any other language necessary to convey the substance of the training) on the seafood HACCP and cGMP regulations and FDA-approved HACCP plans, SSOPs, and Listeria Monitoring Program approved by FDA pursuant to paragraph 6(E), and documented that Defendants, each of their officers, and any other person(s) who performs duties related to receiving, preparing, processing, packing, labeling, holding, and/or distributing food at Defendants' Facility on Defendants' behalf have received such training. Notwithstanding the requirements of this paragraph, Defendant Frantzman need not participate in such training so long as he: (i) is no longer affiliated in any capacity, directly or indirectly, with the Corporate Defendant or any of its affiliates, successors and/or assigns, and (ii) does not engage, directly or indirectly (other than by virtue of his ownership in the Restaurant), in receiving, preparing, processing, packing, labeling, holding, or distributing fish or fishery products; and

(6) submitted to FDA the written HACCP plans and all associated records (including monitoring records), validation studies, SSOPs, Listeria Monitoring Program, and employee training program developed by the Expert(s) pursuant to paragraph 6(C); and documentation demonstrating that the Expert(s) has completed the training described in paragraph 6(C)(5);

(D) Defendants assign continuing responsibility for implementing and monitoring the FDA-approved HACCP plans, SSOPs, and Listeria Monitoring Program 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, implement any necessary correction, and provide such person(s) with the authority to achieve any necessary

correction;

(E) FDA has approved, in writing, the HACCP plan(s), validation studies, SSOPs, Listeria Monitoring Program, and employee training program and documentation developed by the Expert(s), as specified in paragraphs 6(C)(1)-(6). Within thirty (30) business days, or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled, of receiving what Defendants represent to FDA to be their complete and final submission of all the materials required under paragraph 6(C)(6), FDA will notify Defendants in writing of its evaluation of such submission;

(F) Defendants make the FDA-approved HACCP plans, SSOPs, and Listeria Monitoring Program available and accessible to all their employees and any other person(s) who performs duties at Defendants' Facility for Defendants in English and any other language necessary to convey the substance of such documents;

(G) Defendants successfully complete the FDA-approved employee training program described in paragraph 6(C)(5);

(H) Defendants, at their expense, clean and sanitize Defendants' Facility and equipment therein and make improvements, thereby rendering their Facility and equipment suitable for receiving, preparing, processing, packing, holding, labeling, and distributing articles of food in accordance with this Decree, the Act, and all applicable regulations, and Defendants ensure that their 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

during all prior FDA inspections, specifying each FDA observation and Defendants' corrections thereof, and (ii) 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 (which may be, in FDA's sole discretion, by review of documentation and photographs, rather than in-person observation), and in accordance with a written destruction plan approved in writing by FDA prior to implementation, all smoked fish or fishery products in Defendants' custody, control, or possession as of the date of entry of this Decree;

(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. Provided that FDA finds that Defendants' submissions under paragraphs 6(A), (B), (C)(6), (I), and (J) appear to be satisfactory and notifies Defendants of such finding in writing, FDA will initiate the inspection within thirty (30) calendar days of such written notification, or as soon as practicable in the event that FDA representatives are attending to FDA matters that cannot be rescheduled;

(L) Defendants have paid all costs of inspection, analyses, review, investigations, examination, and supervision for FDA's oversight with respect to paragraphs 6(A) through 6(K), 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 6(A) through 6(L) of this Decree, the Act,

and its implementing regulations.

(N) Nothing in this paragraph 6 shall preclude Defendants from receiving, processing, packing, and holding food products for the limited purposes of conducting validation studies, testing equipment, training employees, and conducting analyses that may be necessary to develop standard operating procedures and/or HACCP Plans.

7. Immediately upon resuming operations after completing the requirements of paragraph 6, Defendants shall, in consultation with the Expert(s), continuously implement the FDA-approved HACCP plans, SSOPs, and Listeria Monitoring Program. In the event that Defendants or their Expert(s) determine that the FDA-approved Listeria Monitoring Program 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 organisms such as *L. spp.* and ensure that *L. mono* does not occur in finished products. Defendants further shall comply with the following requirements:

(A) Defendants shall have their finished products tested, by the Laboratory retained pursuant to paragraph 6(A), 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(E);

(2) after satisfying the requirements of paragraph 7(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 7(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 7(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 7(A) to FDA within two (2) calendar days after receipt by Defendants. If any sample analysis conducted pursuant to paragraph 7(A) shows a water phase salt level that does not adhere to the critical limits set forth in the FDA-approved HACCP plans, Defendants shall immediately destroy the affected lot(s) at Defendants' expense, under FDA's supervision (which may be, in FDA's sole discretion, by review of documentation and photographs, rather than in-person observation), and pursuant to a destruction plan approved in writing by FDA prior to implementation. Further, Defendants shall reassess their 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 7(A) anew.

8. 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.

9. Within thirty (30) calendar days after Defendants resume their operations after completing the requirements of paragraph 6, the Expert(s) shall conduct an audit 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 submit an Audit Report documenting all findings to Defendants and FDA concurrently, within twenty-one (21) calendar days after completing the audit. Thereafter, the Expert(s) shall conduct one audit every three (3) months for one year, and then one audit 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 audits annually unless FDA informs Defendants in writing that more frequent expert inspections and reporting are required. If, at any time, Defendants retain a different or additional Expert(s), Defendants shall notify FDA of the identity and credentials of the new Expert(s) within seven (7) calendar days.

(A) During each audit 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.

(B) If the Audit Report contains any observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall, within fifteen (15) business days after receipt of the Audit Report, make all necessary corrections, unless FDA notifies Defendants in writing that a shorter timeframe is required or that a longer timeframe is appropriate. If, after receiving the Audit Report, Defendants believe that a longer time period will be necessary to complete some or all of the corrections, Defendants shall, within ten (10) business days after receiving the Audit Report submit to FDA a proposed schedule for completing the corrections along with explanations for why the additional time is needed. The proposed schedule shall not be effective unless and until FDA approves it in writing.

10. Defendants' operation of the Restaurant and Retail Store are not subject to the requirements of paragraphs 6-9 of this Decree, provided that the Restaurant and Retail Store operate only as retail establishments within the meaning of 21 C.F.R. § 123.3(k)(2)(iii).

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 under 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; 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 take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During inspections, FDA shall be permitted to (i) have immediate access to buildings, equipment, raw ingredients, in-process and finished articles of food, containers, and packaging material therein (ii) take photographs and make video recordings, (iii) take samples of Defendants' raw ingredients, in-process and finished articles of food, containers, and packaging material; and 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 (i) $89.35 per hour and fraction thereof per representative inspection work, (ii) $107.09 per hour or fraction thereof per representative analytical or review work, (iii) $0.575 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 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, audit, 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 immediately to 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) 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 Defendants into compliance with this Decree, the Act, and its implementing regulations.

Any FDA order issued pursuant to this paragraph shall state the noncompliance giving rise to the order.

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, and this Decree, at their Facility in a location where they are readily available for reference and inspection by FDA. Defendant may maintain such records in paper and/or electronic form. 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 either Defendant fails to comply with the provisions of the Act, its implementing regulations, or this Decree, then Defendants shall pay to the United States of America (i) liquidated damages in the sum of one thousand five hundred dollars ($1,500) for each day that such violation continues, (ii) an additional sum of one thousand dollars ($1,000) in liquidated damages per day for each violation of the Act, its implementing regulations, or this Decree (*e.g.*, two violations that occurred for two days would incur liquidated damages of $7,000), and (iii) a further sum in liquidated damages 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

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.

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), or electronic mail with acknowledged receipt, 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, electronic mail acknowledgements, 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 their 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 either 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, certified mail (return receipt requested), or electronic mail with acknowledged receipt 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, proof of service, or electronic mail acknowledgements.

25. Defendants shall address all communications required under this Decree to the Director, New England District Office, Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180, and shall reference this civil action by case name and civil action number and shall prominently mark "Decree Correspondence" in such communication. All

communications from FDA to Defendants shall be addressed to Mill Stream Corporation at 1545 US Highway 1, Hancock, Maine 04640-3831, Ira J. Frantzman at PO Box 96, Sullivan, Maine 04664, as well as to the Individual Successor in the event paragraph 27 is exercised.

26. 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.

27. If Defendant Frantzman ceases to be affiliated in any capacity (*e.g.*, as owner, director, officer, employee, or consultant), directly or indirectly, with the Corporate Defendant or any of its affiliates (including but not limited to its franchises, "doing business as" entities, subsidiaries, successors, or assign), and is no longer engaging in, directly or indirectly, receiving, preparing, processing, packing, labeling, holding, or distributing fish or fishery products, then Defendant Frantzman shall notify FDA in writing and provide supporting documentation.

(A) Defendants may, after FDA has issued written notification to Defendants pursuant to paragraph 6(M) stating that they appear to be in compliance with paragraphs 6(A) - (L) of this Decree, the Act, and its implementing regulations, under the circumstances identified in this paragraph, and upon prior written notice to FDA of thirty (30) business days, jointly petition the Court to release Defendant Frantzman from this Decree, provided that as part of this petition, Defendants shall designate an individual of similar position and responsibility to be substituted as an individual successor ("Individual Successor"), and Defendants and the Individual Successor jointly petition the Court to add the Individual Successor as a Defendant to the Decree.

(B) So long as by the time of the petition, FDA has issued a written notification pursuant to paragraph 6(M) stating that Defendants appear to be in compliance with paragraphs

6(A)-(L) of this Decree, the Act, and its implementing regulations, and so long as FDA finds, in its judgment, at the time of the petition, that: (i) Defendant Frantzman has ceased to be affiliated in any capacity, directly or indirectly, with the Corporate Defendant or any of its affiliates, (ii) Defendant Frantzman has ceased to engage, directly or indirectly, in receiving, preparing, processing, packing, labeling, holding, or distributing fish or fishery products, and (iii) the Individual Successor has a similar position and responsibilities to those of Defendant Frantzman before he ceased any direct or indirect involvement in the Corporate Defendant or any of its affiliates, then Plaintiff will not oppose the release of Defendant Frantzman from this Decree pursuant to such petition. Plaintiff will not oppose the release of Defendant Frantzman from this Decree solely because of his ownership of the Restaurant, provided that Defendants otherwise comply with the terms of this Decree. Defendant Frantzman shall continue to be subject to the terms of this Decree prior to the time the Court releases him from this Decree.

(C) If Defendant Frantzman wishes to be released from this Decree under paragraph 27, then he shall follow the procedures set forth herein only after this Court enters this Decree and FDA has issued a written notification pursuant to paragraph 6(M) stating that Defendants appear to be in compliance with paragraphs 6(A)-(L) of this Decree, the Act, and its implementing regulations. This requirement applies regardless of whether any change in affiliation occurs before or after such entry.

(D) Defendant Frantzman, upon his release from this Decree, may continue to lease the 1545 Facility to the Corporate Defendant without once again requiring him to be subject to this Decree, provided, however, that Defendant Frantzman shall have no role in the operation of the 1545 Facility for directly or indirectly receiving, preparing, processing, packing, holding, labeling, and/or distributing of fish or fishery products. Under no circumstances shall Defendant Frantzman's role as landlord be construed to excuse the Corporate Defendant and/or Individual

Successor from taking any and all actions necessary to comply with this Decree, the Act, and its implementing regulations, including but not limited to making any repairs and/or improvements to the 1545 Facility.

(E) Defendant Frantzman may provide a one-time loan to the Corporate Defendant and/or Individual Successor in the amount of $35,000.00 (USD) without once again requiring Defendant Frantzman to be subject to this Decree, provided, however, that Defendant Frantzman shall have no role in the operation of the Corporate Defendant's and/or Individual Successor's business of receiving, preparing, processing, packing, holding, labeling, and/or distributing of fish or fishery products (including, but not limited to, in the event of default).

(F) An Individual Successor added to this Decree shall be bound by the Decree in the same manner as the Defendants originally named in the Decree.

(G) If Defendant Frantzman is released from this Decree under this paragraph 27 but, at any time while the Decree remains in effect, again decides to engage in, directly or indirectly, receiving, preparing, processing, packing, labeling, holding, or distributing fish or fishery products either at or from Defendants' Facility or any other location, then Defendant Frantzman shall notify FDA in writing no less than thirty (30) days prior to engaging in any such activities and Defendants shall not oppose a motion by Plaintiff to reinstate him as a Defendant who is subject to this Decree and any requirements set forth herein. Plaintiff will not seek Defendant Frantzman's reinstatement as a Defendant to this Decree solely because of his ownership of the Restaurant, provided that the Restaurant does not process fish and fishery products within the meaning of 21 C.F.R. Part 123 and operates only as a retail establishment within the meaning of 21 C.F.R. § 123.3(k)(2)(iii).

28. 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: February 12, 2016

/s/ Jon D. Levy
U.S. DISTRICT JUDGE

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