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.: _____ COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America (the "United States"), by its undersigned attorneys, respectfully represents to this Court as follows:

INTRODUCTION

1. The United States brings this action pursuant to the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to enjoin Mill Stream Corporation, a Maine corporation doing business as Sullivan Harbor Farm ("Mill Stream"), and individual Ira J. (Joel) Frantzman ("Frantzman") (together, "Defendants"), from violating (i) 21 U.S.C. § 331(a), by causing to be introduced or delivered for introduction into interstate commerce food that is adulterated under 21 U.S.C. § 342(a)(4), and (ii) 21 U.S.C. § 331(k), by causing food to become adulterated under 21 U.S.C. § 342(a)(4) while such food is held for sale after shipment of one or more of its components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331, 1337, and 1345.

3. Venue in this judicial district is proper pursuant to 28 U.S.C. §§ 1391(b) and (c).

DEFENDANTS

4. Mill Stream is a Maine corporation that conducts business at a facility located at 1545 US Hwy 1, Hancock, Maine (the "Facility"), which is within this Court's jurisdiction.

5. Frantzman is Mill Stream's president and owner. He is the most responsible person at the firm. Frantzman has authority to respond to FDA's inspectional observations, make corrections, determine the disposition of violative products, and hire and fire employees. He performs his duties at the Facility, which is within this Court's jurisdiction.

6. Defendants prepare, process, pack, hold, and distribute refrigerated, vacuum-packed, ready-to-eat, cold and hot smoked fish or fishery products, including, but not limited to, smoked salmon, trout, and char.

7. Defendants receive raw fish from outside of Maine for purposes of manufacturing their ready-to-eat, smoked fish or fishery products, including salmon from Canada and trout from North Carolina. Defendants sell and ship most of their products to wholesale customers, including customers located in Boston, Massachusetts, and Washington, D.C.

FOOD SAFETY

Clostridium botulinum

8. *Clostridium botulinum* ("*C. bot*") is an anaerobic bacterium that thrives in oxygen-free environments. All people are susceptible to the potent neurotoxin that *C. bot* spores can produce in food. Ingestion of even a small amount of this neurotoxin can cause botulism.

Although the incidence of botulism is rare, the disease can cause paralysis and has a high mortality rate if treatment is not prompt and appropriate.

9. The Act and its implementing regulations require seafood processors such as Defendants to control the risk of *C. bot* toxin formation if the bacterium is reasonably likely to grow in the seafood processors' products. 21 C.F.R. §§ 123.6(a)-(c).

10. *C. bot* is widely distributed in nature and can be found in any raw fish or fishery product. Certain strains of *C. bot*, called "proteolytic" strains, produce offensive odors and tastes in food products. In contrast, "non-proteolytic" strains of *C. bot* do not produce the same sensory signals. Non-proteolytic strains are particularly dangerous because they can grow at refrigeration temperatures and render a food toxic without any signs of spoilage. Toxin formation by non-proteolytic *C. bot* can occur at temperatures above 38° F. To inhibit the growth of non-proteolytic *C. bot*, seafood processors such as Defendants must employ adequate levels of salt or salt/nitrite combinations in brining solutions in conjunction with proper smoking and drying of fish and appropriate temperatures during smoking and refrigeration.

Listeria monocytogenes

11. *Listeria monocytogenes* ("*L. mono*") is the bacterium that causes listeriosis, a disease commonly contracted by eating food contaminated with *L. mono*. Listeriosis can be serious, even fatal, for vulnerable groups such as newborns and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms from listeriosis, and complications from the disease can result in miscarriage or septicemia in the newborn.

12. Unlike many other foodborne microbes, *L. mono* can adapt and grow at refrigeration temperatures. *L. mono* can survive and grow under other adverse conditions, such

as high salt or high acid conditions. *L. mono* can colonize on moist surfaces such as floors, floor drains, processing equipment, and other wet areas. Thus, the presence of *L. mono* in a facility processing ready-to-eat foods presents a particularly significant public health risk.

13. To minimize the potential for *L. mono* contamination, food manufacturers such as Defendants must implement sanitation procedures to prevent contamination of food-contact surfaces and eliminate niches where *L. mono* can become established, grow, and persist. Strict, in-plant sanitation measures are necessary in order to eliminate the organism and prevent its proliferation.

LEGAL FRAMEWORK

14. Defendants' ready-to-eat fish is "food" within the meaning of the Act, 21 U.S.C. § 321(f).

15. Food is adulterated under 21 U.S.C. § 342(a)(4) "if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health."

16. A seafood processor's failure to comply with the requirements of the seafood Hazard Analysis and Critical Control Point ("HACCP") regulations, 21 C.F.R. Part 123, renders its fish or fishery products adulterated under the Act. *See* 21 U.S.C. § 342(a)(4); 21 C.F.R. § 123.6(g).

17. Food is also adulterated under 21 U.S.C. § 342(a)(4) if it is prepared, packed, or held in a facility that does not comply with Current Good Manufacturing Practice ("cGMP") requirements for food. 21 C.F.R. § 110.5(a).

18. The seafood HACCP regulations require every fish and fishery product processor to "conduct, or have conducted for it, a hazard analysis to determine whether there

are food safety hazards that are reasonably likely to occur" during the processing of each kind of fish or fishery product that it produces. 21 C.F.R. § 123.6(a).

19. Whenever a hazard analysis reveals one or more food-safety hazards that are reasonably likely to occur during the processing of seafood, the processor must develop and implement an adequate HACCP plan to control the identified food-safety hazard(s). 21 C.F.R. § 123.6(b). Among other things, a HACCP plan must:

a. include critical control points ("CCPs"), which are points, steps, or procedures in a food-manufacturing process at which controls can be applied to prevent, eliminate, or reduce to an acceptable level, a food-safety hazard, 21 C.F.R. §§ 123.3(b), 123.6(c)(2); and

b. include critical limits at each CCP, which are the maximum or minimum values within which a physical, biological, or chemical parameter must be maintained to prevent, eliminate, or reduce to an acceptable level, the occurrence of the identified food-safety hazard(s), 21 C.F.R. §§ 123.3(c), 123.6(c)(3).

20. A seafood processor also must:

a. have adequate corrective-action plans and take corrective action whenever a deviation from a critical limit occurs, 21 C.F.R. § 123.7;

b. verify that its HACCP plan is adequate to control food-safety hazards reasonably likely to occur and that the plan is being effectively implemented, 21 C.F.R. § 123.8(a); and

c. monitor, with sufficient frequency, sanitation controls and practices used during processing to ensure that such controls and practices conform with the food cGMP requirements specified at 21 C.F.R. Part 110, 21 C.F.R. § 123.11(b).

21. Defendants are subject to the seafood HACCP regulations because they engage in the "processing," as defined at 21 C.F.R. § 123.3(k)(1), of "fish" or "fishery product[s]," as defined at 21 C.F.R. §§ 123.3(d) and (e).

22. Defendants also must comply with cGMP regulations for foods, 21 C.F.R. Part 110, which require, *inter alia*, that (i) food-contact surfaces be cleaned as frequently as necessary to protect against food contamination, 21 C.F.R. § 110.35(d), (ii) work-in-process and packaging be handled in a manner that protects against contamination, 21 C.F.R. §§ 110.80(b)(5), (13), and (iii) no pests be allowed in any area of a food plant, 21 C.F.R. § 110.35(c). *See* 21 C.F.R. § 123.11(b).

DEFENDANTS' VIOLATIONS

23. Defendants violate 21 U.S.C. § 331(a) by causing to be introduced or delivered for introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

24. Defendants violate 21 U.S.C. § 331(k) by causing articles of food to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such articles are held for sale after shipment of one or more of their components in interstate commerce.

25. Defendants' food is adulterated under 21 U.S.C. § 342(a)(4) in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or have been rendered injurious to health. Such insanitary conditions include Defendants' failure to comply with the seafood HACCP regulations, 21 C.F.R. Part 123, by among other deficiencies, failing to adequately control the risk of *C. bot* growth and toxin formation in their vacuum-packed fish or fishery products, and Defendants' failure to implement

effective sanitation controls in accordance with the food cGMP requirements, 21 C.F.R. Part 110.

HISTORY OF VIOLATIONS

26. The U.S. Food and Drug Administration ("FDA") has conducted numerous inspections of Defendants' Facility since 2004. During these inspections, FDA investigators found similar insanitary conditions and repeated violations of the Act and seafood HACCP and/or cGMP regulations.

The Most Recent Inspection, in March/April 2015

27. FDA most recently inspected the Facility between March 31 and April 22, 2015. At the close of that inspection, the FDA investigators issued to Defendants, through Mill Stream's then-General Manager Rebecca Tetlow, a ten-point List of Inspectional Observations ("Form FDA-483") documenting deficiencies such as the following:

a. Failure to include adequate critical limits and to verify that HACCP plans are adequate to control food-safety hazards that are reasonably likely to occur, and that the plans are being effectively implemented, in violation of 21 C.F.R. §§ 123.6(c)(2) and 123.8(a). For example:

i. Defendants' HACCP plans for Cold Smoked Salmon, Pastrami-Style Salmon & Dave's Bacon (hereafter, "HACCP plan for Cold Smoked Salmon"), Hot Smoked Salmon, Hot Smoked Trout, and Smoked Char list critical limits for achieving the minimum 3.5% water phase salt ("WPS") level necessary to control *C. bot* hazards in these smoked-fish products. But FDA investigators observed that Defendants (i) did not have procedures to verify—*i.e.*, scientifically establish and validate—that their processing achieves the minimum WPS level necessary to prevent *C. bot* hazards in all batches of smoked fish and (ii) had made

significant errors in calculating WPS levels. An outside laboratory that Defendants hired to test samples of cold smoked salmon, hot smoked salmon, and hot smoked trout found the WPS levels in those samples to be below the 3.5% critical limit listed in Defendants' HACCP plans. Defendants also conducted their own in-house WPS testing of their cold smoked salmon, hot smoked salmon, and hot smoked trout. FDA then tested cold and hot smoked salmon from lots that had been subjected to Defendants' in-house testing and determined that 5 out of 10 subsamples from the cold smoked salmon sample had WPS levels below 3.5%, and 9 out of 10 subsamples from the hot smoked salmon sample had WPS levels below 3.5%; and

ii. Defendants' HACCP plan for Cold Smoked Salmon states that "the temperature of the fillets on arrival may not exceed 40F." But Defendants lack records of fish temperature during transit and rely on the presence of ice cover at the receiving CCP to determine, instead of actually measuring, fish temperature upon arrival. During FDA's most recent inspection, the FDA investigators observed that the raw salmon fillets that Defendants received were not completely covered in ice. Accordingly, Defendants' temperature critical limit does not ensure that fish are maintained at 40° F or below during transit, in violation of 21 C.F.R. § 123.6(c)(2).

b. Failure to take corrective actions when critical limit deviations occur so as to ensure that no product enters commerce that is either injurious to health or otherwise adulterated as a result of the deviation, in violation of 21 C.F.R. § 123.7(a). For example, Defendants shipped their refrigerated, vacuum-packed smoked salmon, trout, and char products to customers despite the outside laboratory's finding that these products did not meet the minimum 3.5% WPS level necessary to control *C. bot* hazards.

c. Failure to have adequate corrective-action plans, in violation of 21 C.F.R. § 123.7(a), in that Defendants' HACCP plan for Cold Smoked Salmon (i) allows products to be subjected to temperature abuse, (ii) fails to ensure that temperature abused products do not enter interstate commerce, (iii) lists an incomplete corrective action.

d. Failure to have adequate monitoring frequencies at the refrigeration and cold-smoking CCPs in Defendants' Cold Smoked Salmon HACCP plan to ensure that temperature deviations are detected in time to enable effective correction, in violation of 21 C.F.R. § 123.6(c)(4), and failure to have adequate verification procedures at the salting CCP to ensure that all batches of smoked fish meet the 3.5% WPS critical limit, in violation of 21 C.F.R. § 123.8.

e. Failure to implement the verification procedure listed in Defendants' HACCP plan for Cold Smoked Salmon, in violation of 21 C.F.R. §§ 123.6(b), 123.8(a). For example, Defendants failed to conduct quarterly WPS testing for cold smoked salmon, as specified in their HACCP plan, from February 2013 through March 2014, and from May 2014 through August 2014.

f. Failure to monitor the Facility's conditions and practices during processing with sufficient frequency to ensure conformance with cGMP requirements for prevention of (i) cross-contamination from insanitary objects and (ii) protection of food, food packaging material, and food-contact surfaces from adulteration, in violation of 21 C.F.R. § 123.11(b). Specifically, FDA investigators observed, among other things, Defendants':

i. Failure to clean food-contact surfaces as frequently as necessary to protect against contamination of food, in violation of 21 C.F.R. §§ 110.35(d) and 110.80(b). For example, fish debris from the previous day's production was encrusted on the rim of a salt

container and an employee's glove contacted the debris while portioning out salt for gravlax. Additionally, Defendants' cleaning procedures do not include a sanitizing step for the food-contact surfaces of tools and equipment such as parts of the skinner, knives, and plastic trays.

ii. Failure to handle food, work-in-process, and packaging material in a manner that protects against contamination, in violation of 21 C.F.R. § 110.80(b)(5) and (b)(13). Examples include (a) an open rack of cold smoked salmon stored directly under a pipe with frozen condensate build-up, (b) apparent black mold and water staining on the wooden doorframe of the walk-in freezer, through which employees routinely move open trays of smoked salmon, (c) a 50-pound paper salt bag with water stains on the half of the bag that was in contact with the shelf on which it was stored, and (d) water splashing from the processing floor onto a cutting board and the interior surface of plastic bins stored on a drying rack, one of which was then used to hold salmon trim during packaging of the Omega Burst Maple & Pepper product; and

iii. Failure to ensure that no pests are allowed in any area of a food plant, in violation of 21 C.F.R. § 110.35(c). For example, FDA investigators observed rodent excreta pellets too numerous to count on the floor of the Facility in an area where smoker trays are washed and dried.

Previous Inspections

28. FDA conducted numerous inspections of the Facility prior to March/April 2015.

29. FDA inspected the Facility between September 12 and 16, 2014, and issued Defendants a three-item Form FDA-483 listing HACCP deficiencies such as a failure to have adequate monitoring frequencies, in violation of 21 C.F.R. § 123.6(c)(4).

30. FDA inspected the Facility twice in 2011, first between August and September 22, 2011, and then between December 6 and 23, 2011.

31. The December 2011 inspection resulted in FDA's issuance to Defendants, through their then-General Manager Tetlow, a 10-item Form FDA-483 that included the following observations, many of which were similar to the deficiencies observed during the most recent inspection in March/April 2015:

a. Failure to take corrective action when critical limit deviations occur so as to ensure that the affected products do not enter into interstate commerce and that the cause of deviations are corrected;

b. Failure to implement monitoring, recordkeeping, and verification procedures listed in Defendants' HACCP plans; and

c. Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food-contact surfaces, to protect food, packaging material, and other food contact surfaces from contamination by insanitary objects, and to clean non-food-contact surfaces as frequently as necessary to protect against contamination.

32. Moreover, FDA's testing of samples collected from the Facility during the December 2011 inspection revealed *L. mono* in the Facility's environment and on a fish-skinning machine. As a result of that finding, FDA issued to Defendants an Administrative Detention Order pursuant to 21 U.S.C. § 334(h). Defendants subsequently had the affected products destroyed and recalled.

33. In response to the December 2011 inspection, Defendants promised, during a regulatory meeting with FDA on April 2, 2012, to make certain corrections, including

conducting *L. mono* environmental testing. However, FDA's most recent inspection in March/April 2015 revealed that Defendants had discontinued such environmental testing.

34. The August/September 2011 inspection also resulted in the issuance to Defendants of a 10-item Form FDA-483 documenting HACCP or cGMP deficiencies similar to those observed during the March/April 2015 inspection.

35. FDA's inspections of the Facility in 2010, 2008, 2007, 2005, and 2004 also resulted in the issuance to Defendants of Form FDA-483s documenting HACCP or cGMP deficiencies similar to those observed during March/April 2015 inspection.

36. Following the 2007 inspection, FDA held a regulatory meeting with Frantzman to discuss recurring deficiencies at the facility and Defendants' promised corrections.

37. During the 2005 inspection, FDA collected samples that revealed *L. mono* in Defendants' finished cold smoked salmon. Defendants subsequently destroyed the affected lot.

38. Following the 2004 inspection, on May 25, 2004, FDA sent Defendants a Warning Letter notifying them of deficiencies found at the Facility and indicating that FDA may take further regulatory action, including seeking an injunction, if the deficiencies were not promptly corrected.

PRIOR WARNINGS

38. Defendants have received ample notice that their operations violate the law. At the close of each inspection conducted between 2004 and 2015, FDA investigators discussed their observations with Mill Stream's management and issued Defendants Form FDA-483s listing observed objectionable conditions and practices at the Facility. Moreover, as described above, FDA's inspections have resulted in two regulatory meetings and the issuance to Defendants of an Administrative Detention Order and a Warning Letter.

39. Defendants are aware of their history of non-compliance with the Act.

40. Defendants repeatedly have promised to comply with applicable statutory and regulatory requirements. However, Defendants' deviations from the seafood HACCP regulations and cGMP requirements remain systemic and persistent. As a result, Defendants continue to fail to bring their operations into compliance with the law.

41. The United States believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and (k).

WHEREFORE, the United States requests this Court:

I. order that 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 Court's Order by personal service or otherwise, cease receiving, preparing, processing, packing, labeling, holding, and distributing food at or from the facility or at any other location(s) at or from which Defendants, now or in the future, receive, prepare, process, pack, label, hold, and distribute articles of food, unless and until Defendants bring their receiving, preparing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and applicable regulations, to FDA's satisfaction;

II. permanently restrain and enjoin, under 21 U.S.C. § 332(a), 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 Court's Order by personal service or otherwise, from directly or indirectly violating 21 U.S.C.

§ 331(a) by introducing or delivering for introduction into interstate commerce, or the causing thereof, any article of food that is adulterated within the meaning of 21 U.S.C. § 342(a)(4);

III. permanently restrain and enjoin, under 21 U.S.C. § 332(a), 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 Court's Order by personal service or otherwise, from directly or indirectly violating 21 U.S.C. § 331(k) by adulterating, or causing the adulteration of, within the meaning of 21 U.S.C. § 342(a)(4), any article of food while such article of food is held for sale after shipment of one or more of its components in interstate commerce;

IV. order that FDA be authorized pursuant to the issued injunction to inspect Defendants' place(s) of business and all records relating to the receiving, preparing, processing, packing, labeling, holding, and distribution of food to ensure continuing compliance with the terms of the injunction, the costs of such inspection to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

V. award the United States its costs incurred in pursuing this action, including the costs of investigation to date, and such other relief as this Court deems just and proper.

Dated this 10th day of February, 2016.

Respectfully submitted,

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