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VIA FEDERAL EXPRESS

Our Reference: 2918310

September 11, 2002

James W. Lucas, President/Owner
Lucas Wharf, Inc.
595 Highway 1
Bodega Bay, California 94923

WARNING LETTER

On March 5, 7, 13, 19, 22, and 25, 2002, the U.S. Food and Drug Administration (FDA) inspected your seafood processing facility, located at 595 Highway 1, Bodega Bay, CA. We found that you had serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations caused your cold-smoked salmon (lox), kippered smoked salmon, tuna, smoked tuna, and cooked crab to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fishery products had been prepared, packed, and held under insanitary conditions whereby they may have been rendered injurious to health.

You may find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout, which gives information on how to obtain the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. This guidance is also available electronically through links in FDA's home page.

Your serious HACCP deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b).
 - a. However, your firm did not have a HACCP plan for refrigerated, ready-to-eat, vacuum-packaged, cold-smoked salmon (Lox) to control the food safety hazards of pathogen growth and toxin formation (i.e., *Clostridium Botulinum* toxin formation).
 - b. However, your firm did not have a HACCP plan for refrigerated, ready-to-eat, vacuum-packaged, hot-smoked tuna to control the food safety hazards of

histamine formation, pathogen growth, and toxin formation (i.e., *Clostridium Botulinum* toxin formation).

2. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c)(1). However, your firm's HACCP plan for refrigerated, ready-to-eat, vacuum-packaged kippered smoked salmon (hot-smoked salmon) did not list the food safety hazard of *Clostridium botulinum* toxin formation at the brining and cooking critical control points. A food safety hazard is defined in 21 CFR Part 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption."

Clostridium botulinum toxin formation is a significant hazard for reduced oxygen packaged fishery products (i.e. vacuum packaged products). Please refer to "CONTROL STRATEGY EXAMPLE 1--SALTING/SMOKING, Chapter 13 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, p. 175. We have enclosed a copy of Chapter 13 for your ready reference.

3. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for Frozen at Sea Albacore Tuna, a scombrotoxin-forming fish, did not list the critical control points of thawing and refrigerated storage for controlling the food safety hazard of histamine formation. A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels."

FDA recommends critical control points at processing steps where the potential for cumulative effects of time/temperature abuse are reasonably likely to occur and result in unsafe levels of histamine in your Sea Albacore Tuna product. Refer to Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, p. 87.

4. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). A critical limit is defined in 21 CFR Part 123.3 (c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."
 - a. However, your firm's HACCP plan for Frozen at Sea Albacore Tuna listed a critical limit, "All lots received are accompanied by harvest vessel records that show cooling and freezing of fish to proper levels (50° in 6 hours) (40° in 18 hours)," at the receiving critical control point that is not adequate to control histamine formation. FDA recommends cooling to 50°F in 6 hours, and to 40°F in 12 hours.

As a primary (first) processor, the critical limits for your receipt of fish from harvest vessels should ensure that all lots of fish are documented with appropriate harvest vessel records.

Please refer to "CONTROL STRATEGY EXAMPLE 1 - HARVEST VESSEL CONTROL," Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001, pp. 88-89 for FDA's recommendation for critical limits for receipt by primary (first) processor. We have enclosed a copy of Chapter 7 for your ready reference.

- b. However, your firm's HACCP plan for cooked crab listed a critical limit, "Chill crab to internal temperature of ___°" at the Cooling critical control point that is not adequate to control pathogen growth. Refer to Table #A-2, for time and temperature parameters to control pathogen growth and toxin formation in the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

With regard to your HACCP plan for kippered smoked salmon, we recommend that you replace "Min. core temp per process schedule" with "145° for 30 minutes" as your critical limits for the Cooking critical control point.

5. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, you did not list the method you will use to assure that your critical limit minimum temperature is met, such as, "water observed at rolling boil" or "a continuous monitoring temperature device."
6. You must implement the record-keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b).
 - a. However, your firm did not record monitoring observations at the brining, cooking, cooling, and storage critical control points to control the food safety hazard of pathogen growth and toxin formation (specifically, *Clostridium botulinum* toxin formation at the storage critical control point) in your HACCP plan for refrigerated, ready-to-eat, vacuum-packaged kippered smoked salmon (hot-smoked salmon).
 - b. However, your firm did not record monitoring observations at the receiving critical control point to control the food safety hazard of histamine formation in your HACCP plan for Frozen at Sea Albacore Tuna.
 - c. However, your firm did not record monitoring observations at the cooking and storage critical control points to control the food safety hazard of pathogens in your HACCP plan for cooked crab.
7. You must maintain sanitation control records that document the monitoring and corrections applied to the following to comply with 21 CFR 123.11(c). However,

your firm failed to document your sanitation monitoring observations for the eight key areas of sanitation as evidenced by your lack of sanitation monitoring records for the following:

- Safety of water
- Condition and cleanliness of food-contact surfaces
- Prevention of cross-contamination
- Maintenance of hand-washing, hand-sanitizing, and toilet facilities
- Protection from adulterants
- Labeling, storage, and use of toxic compounds
- Employee health conditions
- Exclusion of pests

8. Because you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for cooked crab at the refrigerated storage critical control point to control pathogen growth was not adequate. This corrective action does not ensure that the adulterated product will not enter commerce.

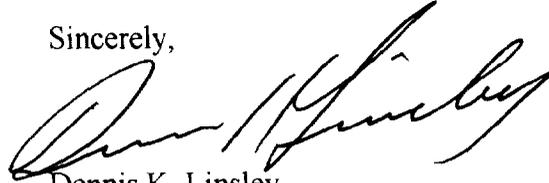
At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with Shane J. Lucas, Fisheries Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR 110) and that your products are properly labeled (21 CFR 101).

Over six months have elapsed since FDA inspection which should have been sufficient time to correct the violations. We may take further action if you have not corrected these violations. For instance, we may move to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

cc: Shane J. Lucas, Fisheries Manager
Lucas Wharf Fisheries
595 Highway 1
Bodega Bay, California 94923

Enclosures:

- Handout on Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition
- Copy of Chapter 13 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001
- Copy of Chapter 7 of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001
- Table #A-2, Time/Temperature Guidance for Controlling Pathogen Growth and Toxin Formation in Seafoods
- Form FDA 483