



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

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San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

Our Reference: FEI 3003974052
Pacific American Fish Company, Inc.
Dba PAFCO-San Francisco

August 27, 2003

Peter Y. Huh, President
Pacific American Fish Company, Inc.
620 South Gladys Avenue
Los Angeles, California 90021

WARNING LETTER

Dear Mr. Huh:

On May 27, 28, and 29, 2003, we inspected your seafood processing facility, Pacific American Fish Company, Inc. dba PAFCO-San Francisco, located at Pier 45, Shed B-5, San Francisco, California. We found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish (e.g., tuna and Mahimahi), farm raised striped bass, and farmed white sturgeon are adulterated, in that the products have been prepared, packed, or 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. The attached handout explains how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, Third Edition, June 2001. We listed the deviations on a Form FDA 483 and discussed them with Mr. Angel

Contreras, General Manager, at the conclusion of the inspection. We are enclosing a copy of the Form FDA 483 for your reference.

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 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). A food safety hazard is defined in 21 CFR 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for "Scombroid" fish does not list the food safety hazard of pathogen growth and toxin formation at the Cooler Storage Critical Control Point for those fish intended to be consumed raw.

- (2) 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 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 "Scombroid" fish lists a critical limit at the "Receiving" Critical Control Point that is not adequate to control pathogen growth and histamine formation as a result of time/temperature abuse. Your firm's HACCP plan lists a critical limit that the internal temperature of incoming product must not exceed 40°F. FDA recommends that for fish delivered refrigerated (not frozen) with a transit time of four hours or less, the internal temperature of a representative number of fish in the lot be 40°F or below at the time of delivery. For scombrotoxin forming species received with a transit time greater than four hours, FDA recommends the firm check the adequacy of ice or cooling media at the time of delivery, or ensure that all lots are accompanied by transportation records that show that the fish have been held below 40°F throughout transit.

- b. However, your corrective action plan for “Scombroid” fish lists a corrective action at the Cooler Storage Critical Control Point as follows: “If there is any temp deviation, maintenance dept will be notified immediately. The product will be check for proper icing to ensure that the product temp stays below [REDACTED].” This corrective action does not have appropriate provisions to determine product safety and proper disposition of potentially hazardous product when the critical limit is exceeded. In addition to your listed corrective action plan, FDA recommends that you destroy the product, divert the product to non-food use, or perform histamine analysis to determine the acceptability of the lot to determine product safety and disposition of potentially hazardous product.
- (5) You must implement the record keeping system that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Cooler Storage Critical Control Point to control histamine formation as required by your HACCP plan for “Scombroid” fish.
- (6) You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation monitoring records for any of the eight key areas of sanitation required for the processing of refrigerated tuna which may be consumed raw.

Sufficient time has passed, since our inspection of May 2003 and our presentation of the FDA 483 Inspectional Observations to [REDACTED], to correct the violations at your facility. If you have not made corrections, you must immediately take appropriate steps to correct the violations. We may initiate regulatory action without further notice if you do not correct these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

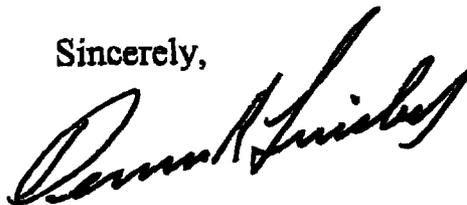
Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things that you are doing to correct the deviation. You may wish to include in your response

documentation such as copies of your HACCP plans, temperature monitoring records, or other useful information 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.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, 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. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosures:

Form FDA 483
Handout on Fish & Fisheries Products Hazards & Controls Guidance,
3rd edition, June 2001

cc: Via Certified Mail
Angel Contreras, General Manager
Pacific American Fish Company, Inc.
P.O. Box 2627
San Francisco, CA 94126-2627