



PACIFIC AMERICAN FISH  
CO., INC.

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September 9, 2003

U.S. Food and Drug Administration  
Ms. Erlinda N. Figueroa  
Compliance Officer  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070

Reference: FEI 3003974052  
Pacific American Fish Company, Inc.  
Db a PAFCO-San Francisco

### RESPONSE TO WARNING LETTER August 27, 2003

Dear Ms. Figueroa,

The following corrections have been made to bring our seafood processing facility, Pacific American Fish Company, Inc. dba PAFCO-San Francisco, located at Pier 45, Shed B-5, San Francisco, California, into compliance with Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123):

1. To conform to 21 CFR 123.6(a) and (c)(1) we have conducted a HACCP review and added a critical control point section dealing with chilled storage of "Scombroid" fish on page 20 of our HACCP Manual.
2. To conform to 21 CFR 123.6(c)(3) we have changed the maximum allowable temperature, for fresh fish, at every stage that the product is within our control to 40°F in our HACCP Manual.
  - a. At the time of delivery all fresh fish must maintain a temperature below 40°F and all documentation must show that this maximum temperature has been maintained.
  - b. The chilled storage maximum allowable temperature has been changed to 40°F in our HACCP Manual.
3. To conform to 21 CFR 123.6(c)(4) we have begun monitoring the temperature of the chilled storage via continuous data logger system with an alarm function that will alert a responsible party if the maximum allowable cooler temperature has been exceeded. This system has been purchased and will be installed by September 16, 2003. Until the system is operational a visual check of the current thermometers is performed and recorded twice a day.

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4. To conform to 21 CFR 123.7(b) we have changed our corrective action plan to the following:
  - a. Product, which does not comply with the standard of 40°F, will be rejected and PAFCO will discontinue the use of the supplier and/or carrier until a guarantee that the transportation practices have become adequate to keep the internal temperature of the product below 40°F has been given.
  - b. If the temperature of the chilled storage rises above 40°F for more than one hour, the product will be discarded and no fish will be kept in the chilled storage until repairs are made.
5. To conform to 21 CFR 123.6(b) we have begun monitoring our facilities as put forth in our HACCP Manual.
6. To conform to 21 CFR 123.11(c) we have updated our SSOPs to reflect cGMP procedures and monitoring requirements.

The preceding points are the ones specifically noted in the warning letter sent to Peter Y. Huh, President, Pacific American Fish Company, Inc., by Dennis K. Linsley, District Director, San Francisco District, Department of Health & Human Services on August 27, 2003. Each of the observations noted on Form FDA 483 from the inspection performed from May 27, 2003 to May 29, 2003 have been noted and corrected as per our understanding of the Form FDA 483 observations and the "Fish and Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001.

Enclosed please find a copy of the current HACCP Manual for PAFCO-San Francisco and a copy of the purchase order for data logging thermometers dated September 4, 2003.

If you have any questions please contact me at (213) 623-3433 ext. 186.

Sincerely,



Christopher Maher  
QA Technician  
Pacific American Fish Company, Inc.