DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administra
942600
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS
Our Reference: 3001836723

August 8, 2003

Linda M. Bowser, Owner
Pacific Seafood
678 Grinder Way, #A
Stockton, California 95206

WARNING LETTER

Dear Ms. Bowser:

On May 20, 21, 22, 23, 27, and 28, 2003, we inspected your seafood processing facility, located at 678 Grinder Way #A, Stockton, California. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 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 fish and fishery products 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 Regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at any of the critical control points (receiving, cooling, storage) to control the various hazards listed in your HACCP plan for fish and fishery products.

   Our review of your blank monitoring record forms and HACCP plan has also determined that some of the forms do not include places to record observations of whether your critical limit is being met or not. For example, your receiving

record does not have a place to record internal temperatures or adequacy of the ice.

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 lists a critical limit "All known histamine-producing fish will not be accepted if the temperature is higher than [redacted] degrees F." that is inadequate to control histamine formation. FDA recommends a critical limit of 40 degrees F as an adequate control for histamine formation at your Receiving critical control point.

   b. However, your firm's HACCP plan lists a critical limit "All fresh products will be maintained at a temperature not to exceed [redacted] degrees F and will be processed or shipped within the following time frame from the date or receipt." at the Chilled Storage critical control point that is not adequate to control histamine formation in Scombrotoxin forming species and *Clostridium botulinum* in the vacuum packed smoked fish you store.

      FDA currently recommends that cooler temperatures be maintained at 40 degrees or less for Scombrotoxin forming species and vacuum packed smoked fish. In addition, FDA does not consider monitoring internal temperatures an adequate method of assuring that Scombrotoxin forming fish and vacuum packed smoked fish are held at consistently safe temperatures. We currently recommend that either the ambient temperature in the cooler be monitored with a <u>continuous</u> monitoring system <u>or</u> that the seafood be surrounded in ice and the adequacy of the ice be checked twice a day.

   c. However, your firm's HACCP plan fails to list a critical limit at the Receiving critical control point to control *Clostridium botulinum* in the vacuum packed refrigerated smoked fish your receive.

      FDA recommends you monitor the adequacy of the cooling media surrounding the fish during shipment <u>or</u> that you require your transporter to monitor shipping temperatures by some method that assures that the fish were maintained at safe temperatures throughout transport. FDA recommends a critical limit of 40 degrees F if you chose to monitor transportation temperature.

3. You must take corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). Sections 123.7(b) and (c) require that a corrective action ensures that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and that the cause of the deviation is corrected. Since 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,

a. Your corrective action plan for fish and fishery products at the Receiving critical control point fails to adequately control the hazard of histamine formation. Your listed temperature in the corrective action plan (i.e. [redacted] degrees) exceeds your listed critical limit of [redacted] degrees. Corrective action(s) must be taken when your critical limit is exceeded. In addition, evaluating the fish for decomposition is not a reliable method for assuring detection of histamine formation. Page 96 in Chapter 7 of the Guidance provides examples of appropriate corrective actions.

b. Your corrective action plan for fish and fishery products at the Chilled Storage critical control point is not adequate to control histamine formation and *Clostridium botulinum*. You do not list how you will correct the cause of the deviation. Your listed temperature in the corrective action plan (i.e. [redacted] degrees) exceeds your listed critical limit of [redacted] degrees. Corrective action(s) must be taken when your critical limit is exceeded. In addition, FDA does not consider sensory evaluations to be adequate methods for determining the presence of either of these hazards.

At the conclusion of the inspection, the deviations were listed on Form FDA 483 and discussed with you. 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 regulation, and the Current Good Manufacturing Practice regulation (21 CFR 110).

We may take further action if you do not promptly correct these violations. 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 you are doing to correct these deviations. You may wish to include in your response documentation 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.

Moreover, please note that our review of your HACCP plan has determined that you appear to have written one plan that is to apply to all the products you process, irrespective of the hazards and processes associated with the products. This is a violation of 21 CFR 123.6(b)(2). Your plans must be specific to each kind of fish and fishery product. The plan may group kinds of fish and fishery products together only if the food safety hazards, critical control points, critical limits and procedures are identical for all fish and fishery products so grouped. Your plan includes refrigerated raw Scombrotoxin forming species; refrigerated cooked ready-to-eat crab, crustacean and lobster meat; and vacuum packed smoked fish. The hazards associated with these products are different. The critical control points necessary for your cooked ready to eat crab and lobster meat differ from the ones necessary for Scombrotoxin forming species and vacuum packed smoked fish.

Furthermore, during the May 2003 inspection, you told our investigator that you no longer cook seafood. We recommend that your plan be updated to reflect this. If you

decide to begin your cooking process again, please be aware that significant deviations exist with the cooking and cooling critical control point that must be corrected to ensure that you produce a safe product.

Please send your reply 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

Enclosure:
Form FDA 483