



VIA FEDERAL EXPRESS

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Our Reference: 2938920 & 2953776

April 17, 2002

Daniel D. Strazzullo, President
Peninsula Seafood of San Bruno, Inc.
Dba All Shores Seafood
135 El Camino Real
San Bruno, California 94066

WARNING LETTER

Dear Mr. Strazzullo:

On December 18, 19, and 21, 2001, we inspected your seafood processing facility at the above address and your seafood warehouse located at Pier 45, Shed B-5, San Francisco, California, and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your tuna, Mahi-mahi, and refrigerated ready-to-eat herring fishery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish have been prepared, packed, and held under insanitary conditions whereby they may be 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 on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001. We listed the deviations on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Subsequent to the discussion, you provided us with your firm's HACCP plans for histamine producing fish and ready to eat seafood products. Although you provided us with these HACCP plans, implementation is also a critical portion of the seafood regulations. We were not able to confirm whether these HACCP plans have been implemented as is.

District review of your firm's HACCP plans found serious deviations as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3).
 - a) However, your firm's HACCP plan for "Ready to eat product," specifically Herring in Sour Cream and Herring in Wine Sauce, lists a critical limit at the

Receiving and Storage critical control point (CCP) that is not adequate to control pathogens. Your HACCP plan lists a critical limit of 45°F as a maximum product temperature during the receipt and storage of ready-to-eat products. First, FDA recommends that you list Receiving and Storage as separate critical control points. The controls at these critical control points are not entirely the same. Second, the product temperature of 45°F has not been found to be adequate in the control of pathogen growth for products intended to be held under refrigeration. A temperature of 40°F or less is recommended for maintaining the safety of the product. Additionally, because you purchase fish from other processors, you are also responsible for ensuring that the fish were handled in a safe manner during transport. At the Receiving CCP, FDA recommends that you either maintain transportation records for all lots showing that fish and fishery products have been held at 40°F or less throughout transit, or check the adequacy of ice or cooling medium in a representative number of boxes [the cooling medium must completely surround the product]. We recommend that you refer to Chapter 12 of the Fish and Fisheries Products Hazards and Controls Guide (the Guide) for information relating to the appropriate monitoring procedures, verification procedures, corrective actions, and record keeping system to ensure compliance with the critical limits for each critical control point.

- b) However, your firm's HACCP plan for "All fin fish with Scombrototoxin Formation," specifically tuna and Mahi-mahi, lists a critical limit at the Receiving and Storage CCP that is not adequate to control histamine formation due to time/temperature abuse. Product temperature critical limit of 45°F is not adequate to control the food safety hazard of histamine formation. FDA recommends that you refer to Chapter 7 of the Guide for information relating to control strategies for histamine formation.
2. You must have a HACCP plan that lists the monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plans for "Ready to eat product" and "All fin fish with Scombrototoxin Formation" list monitoring procedures and frequencies at the Receiving and Storage CCP that are not adequate to control the food safety hazards associated with these products (pathogens and histamine formation respectively). During refrigerated storage of these products, FDA recommends continuous monitoring of the temperature. You may either monitor the adequacy of ice or cooling media twice a day, or monitor the temperature of the storage chamber continuously by means of a temperature data recorder or by using an alarm system.

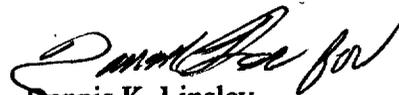
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of the revised 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 (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic 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:

FDA 483

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