



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

93935d

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

VIA FEDERAL EXPRESS

Our Reference: FEI 3000203398
Pacific Fresh Sea Food Company

March 28, 2003

Frank M. Dulcich, President
Pacific Seafood Group
3220 First Avenue, S.W.
Portland, Oregon 97201

WARNING LETTER

Dear Mr. Dulcich:

On February 14 and 24, 2003, we inspected your seafood processing facility, Pacific Fresh Sea Food Company, located at 1906 West Belmont Avenue, Fresno, California. We found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 C.F.R. Part 123). In accordance with 21 C.F.R. § 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operates 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, ready-to-eat fishery products, e.g., crabmeat, shrimp, smoked salmon, and your refrigerated histamine forming fish, e.g., tuna, and Mahimahi 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. 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 Mr. Larry L. Perkins, Account Manager, at the conclusion of the inspection.

We are enclosing a copy of the 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 you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 C.F.R. § 123.6(a) and (b). However, your firm does not have a HACCP plan for:
 - (a) Refrigerated, ready-to-eat fishery products such as crabmeat, shrimp, and smoked salmon, to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse;
 - (b) Refrigerated, vacuum packed, ready-to-eat Smoked Salmon, to control the food safety hazard of *Clostridium botulinum* growth and toxin formation as a result of time/temperature abuse;
 - (c) Refrigerated histamine forming fish such as tuna, and Mahimahi, to control the food safety hazard of histamine formation as a result of time/temperature abuse.
2. You must adequately monitor and maintain records of monitoring sanitation conditions and practices during processing, to comply with 21 C.F.R. § 123.11(b) and (c). However, your firm did not monitor and has no sanitation monitoring records required for the processing of refrigerated ready-to-eat fishery products.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct the problem. For instance, we may take further action to seize your products 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 C.F.R. 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,



Darrell T. Lee
Acting District Director
San Francisco District

Enclosures:

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

cc: Larry L. Perkins, Account Manager
Pacific Fresh Sea Food Company
1906 West Belmont Avenue
Fresno, California 93728