



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

94378d

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

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

Our Reference: FEI 3001600986

October 23, 2003

James P. Schach, President
Superior Seafood of San Francisco, Inc.
P. O. Box 320571
San Francisco, California 94123

WARNING LETTER

Dear Mr. Schach:

On August 8, 12, and 20, 2003, we inspected your seafood processing facility located at Pier 33 Bay 9, San Francisco, California. We found that you have a serious deviation from the seafood Hazard Analysis Critical Control Point (HACCP) regulations in 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 fish and 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 Albacore tuna is adulterated, in that the fish 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 attached handout explains how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.

At the conclusion of the inspection, we listed the deviations on a Form FDA-483 and discussed them with [REDACTED]. A copy of the Form FDA-483 is attached for your reference. Your serious HACCP deviation was as follows:

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 likely to occur, to comply with 21 CFR 123.6(a) and (b). However, your firm does not have a HACCP plan for Albacore tuna to control histamine formation as a result of time/temperature abuse.

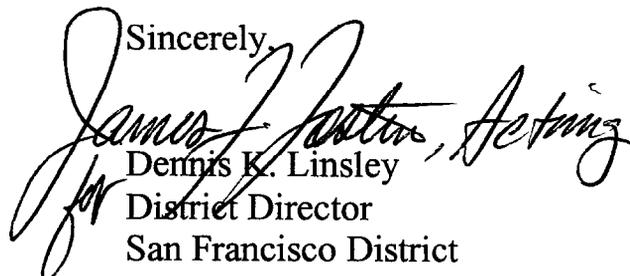
You must immediately take appropriate steps to correct the violation. We may take further action if you do not promptly correct the violation. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

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 the deviation. You may wish to include in your response documentation such as copies of your HACCP plan, HACCP 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 current Good Manufacturing Practice (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,

James P. Schach, Acting
for
Dennis K. Linsley
District Director
San Francisco District