



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

M3959M

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

**VIA FEDERAL EXPRESS**

July 18, 2000

Our Reference: 2919865

Elizabeth Kaneshiro, President  
M. Kane's Fish Market, Inc.  
117-B Ahui Street  
Honolulu, Hawaii 96813

**WARNING LETTER**

Dear Mrs. Kaneshiro:

On December 21 and 22, 1999, we inspected your seafood processing facility and found that you have serious deviations from the Seafood HACCP regulations in Title 21 of the Code of Federal Regulations (21 CFR Part 123). These deviations, cause your dried Jack Mackerel and dried Skipjack Tuna 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 and fishery products have been prepared, packed, or held under insanitary conditions whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them in detail with Mr. Robert K. Kaneshiro, HACCP Coordinator, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference and action. Your serious HACCP violations are as follows:

1. You must have a written HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b) and (c)(1). However, your firm's HACCP plans for dried tuna and mackerel do not list the food safety hazard of pathogen growth and toxin formation, including *Staphylococcus aureus* toxin formation, as a result of inadequate drying.
2. You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plans for dried tuna and mackerel do not list the critical control points (CCPs) of thawing, butchering and filleting, and brining, for controlling the food safety hazard of histamine formation as a result of time/temperature abuse.

3. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records as evidenced by the date of the last sanitation record maintained by your firm, dated January 14, 1999.

We observed similar deviations during the previous inspection of your facility on July 16 and 17, 1998. At the conclusion of the inspection, we presented a written list of inspectional observations and discussed the findings with Mr. Robert K. Kaneshiro and you. We also reported these HACCP deviations to you, by correspondence from this office, on November 12, 1998. However, we did not receive any response from your firm. Our recent inspection shows that your firm did not correct the HACCP deficiencies cited in our previous letter.

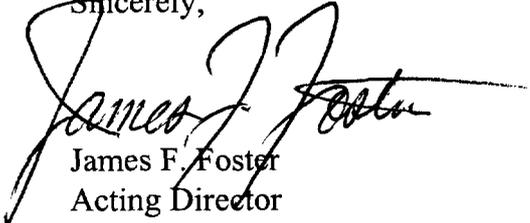
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and /or enjoin your firm from operating.

Please respond in writing within three (3) weeks from 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 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. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act, and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



James F. Foster  
Acting Director  
San Francisco District

cc: Robert K. Kaneshiro, HACCP Coordinator