



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

M28347

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

**VIA FEDERAL EXPRESS**

July 30, 1999

Our Reference: 2920627

Paul T. Nishimoto, President  
Fishland Market Ltd.  
117C Ahi Street  
Honolulu, HI 96813

**WARNING LETTER**

Dear Mr. Nishimoto:

On May 10 and May 12, 1999, Investigator John Cook and Biologist Elsa Yu of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations as defined in Title 21 of the Code of Federal Regulations (CFR), Part 123 and the Good Manufacturing Practices (GMP) requirements for foods as defined in Title 21 of the Code of Federal Regulations, Part 110.

Fresh tuna and other scombroid fish processed at your facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that you failed to operate in accordance with the requirements of Title 21, Code of Federal Regulations (21 CFR) Part 123. At the conclusion of the inspection ending May 12, 1999, the FDA investigators provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501), and the FDA 482 (Inspectional Observations) and discussed the findings with you. The observation of concern to us is as follows:

1. Failure to implement the monitoring procedures specified in your HACCP plan for the cooler storage of histamine forming species [21 CFR 123.6(c)(7)]. The cooler temperature is not always monitored, specifically, the continuous recording chart in the cooler has been inoperable since April 12, 1999.

Deviations from Good Manufacturing Practices were observed, specifically:

1. Failure to have effective quality control operations to ensure that food is fit for human consumption (21 CFR 110.80). Organoleptic examination of 40 swordfish revealed that 25 fish were decomposed. These fish were stored in your cooler and processing room. You told the investigators that all products held at your facility are for distribution.

Similar deviations were observed during your previous FDA inspection on July 13 and 14, 1998. Following the July 1998 inspection, the FDA investigators presented a written list of inspectional observations and discussed the findings with you. These deviations were also reported to you by correspondence from this office on September 17, 1998. We are concerned that you have not corrected all of the HACCP deviations cited in our previous letter although you told the investigators that you would correct them. We acknowledge, however, your efforts to correct several of the deviations found previously.

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

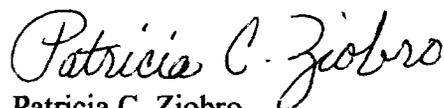
Please advise us in writing, within fifteen working day of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

In addition to the violations mentioned above, there are other HACCP deviations which should be brought to your attention. These deviations are as follows:

1. Failure to calibrate thermometers used to monitor critical control points [21 CFR 123.8(a)(2)(ii)].
2. Failure to maintain sanitation control records that document the monitoring and corrections of sanitation conditions and practices during processing [21 CFR 123.11(c)]. Specifically, no documentation was available to show monitoring of the safety of plant water for ice production and processing, control of employee health conditions, and exclusion of pests.

We encourage you to make the necessary improvements to your HACCP system as soon as possible. If you have questions regarding the implementation of the HACCP regulation, you may contact Mr. John Cook, Investigator, at (808) 541-2662 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,



Patricia C. Ziobro  
Director  
San Francisco District

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