



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**Public Health Service  
Food and Drug Administration**

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

**VIA FEDERAL EXPRESS**

September 16, 1999

Our Reference: 2938878

Thomas T. Mukaigawa, President  
Monarch Seafoods, Inc.  
515 Kalihi Street  
Honolulu, HI 96819

**WARNING LETTER**

Dear Mr. Mukaigawa:

On June 9 and June 10, 1999, Investigator Lynn Wong 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.

At the conclusion of the inspection, the FDA investigator provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501), and the FDA 483 (Inspectional Observations) and discussed the findings with you. The deviation is as follows:

1. Since August 1998, your firm has not followed the monitoring procedures listed in your HACCP plan for scombroid fish to control histamine formation, i.e., recording internal fish temperatures at receiving and cooler storage temperatures. You must implement the monitoring procedures listed in your HACCP plan in order to comply with 21 CFR 123.6(b) and (c)(4).

Similar deviations were observed during your previous FDA inspection on July 22 and 23, 1998. Following the July 1998 inspection, the FDA investigator presented a written list of inspectional observations and discussed the findings with you. Our office also reported these deviations to you by correspondence on August 14, 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.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility as the President of your establishment to ensure adherence to each requirement of the Act and regulations.

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 (15) 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).

Sincerely,

A handwritten signature in cursive script, appearing to read "Patricia C. Ziobro for".

Patricia C. Ziobro  
District Director  
San Francisco District