



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

6/17/01

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

VIA FEDERAL EXPRESS

April 19, 2001

Our Reference: 2953579

Bruce W. Johnson, President
Fresh Island Fish Company, Inc.
312-G Alamaha Street
Kahului, Hawaii 96732

WARNING LETTER

Dear Mr. Johnson:

On February 15, 20, and 21, 2001, we inspected your seafood processing facility located at 3100 Ualena Street, Honolulu, Hawaii. We conducted this inspection to determine your compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. The deficiencies cause your histamine forming fish such as Mahi-mahi, Ahi tuna, and Wahoo 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 have been prepared, packed or held under insanitary conditions whereby they may be rendered injurious to health. We listed the deficiencies on a Form FDA 483 and discussed them with Victor J. Daubert, Operations Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP deficiencies are as follows:

1. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for histamine-forming species lists a critical limit at receiving, "check for refrigeration" and does not list the procedure that will be used to monitor the critical limit. We wish to remind you that since your firm's HACCP plan lists monitoring of internal temperature as a control for histamine formation, you must maintain adequate

records documenting those temperatures. Your firm received Mahi-mahi from [REDACTED] on January 22, 2001, and from [REDACTED] on February 13, 2001, but did not record the receiving temperatures.

2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for histamine-forming species at the Receiving and Cold Storage CCPs relies on sensory evaluation and a periodic histamine testing to determine the acceptability of the fish. Sensory evaluation alone is not a reliable method for the detection of histamine. The appropriate corrective action for fish failing to meet a critical limit is to either: a) reject the lot; b) hold the lot until the total time/temperature exposure can be determined and evaluated; or, c) test the lot for histamine and reject the lot if any fish is over 50 parts per million.

3. You must adequately monitor and document sanitation conditions and practices, to comply with 21 CFR 123.11(b) and (c). However, your firm did not monitor and maintain records related to the safety of water and the exclusion of pests from your facility to ensure sanitation control during processing.

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 these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

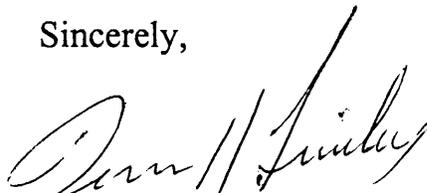
Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation 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 deficiencies.

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,

A handwritten signature in cursive script, appearing to read "Dennis K. Linsley".

Dennis K. Linsley

Director

San Francisco District

Enclosure

cc: Mr. Victor J. Daubert, Operations Manager
Fresh Island Fish Company, Inc.
3100 Ualena Street
Honolulu, Hawaii 96819