



VIA FEDERAL EXPRESS

December 15, 2000

Our Reference: 2954507

Richard F. Tam Sing, President
Upcountry Fishery, Inc.
190-E Alamaha Street
Kahului, Hawaii 96732

WARNING LETTER

Dear Mr. Tam Sing:

On June 29 and 30, 2000, we inspected your seafood processing facility. We conducted this inspection to determine compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your histamine forming fish such as Mahi-mahi, Wahoo, Marlin, and 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 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 with you at the conclusion of the inspection. Your serious HACCP violations are as follows:

1. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for histamine forming fish lists a monitoring procedure at the Receiving critical control point (CCP) that is not adequate to control histamine formation prior to receiving the fish.
2. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Receiving, Raw and Finished Product Storage, or the Cutting and

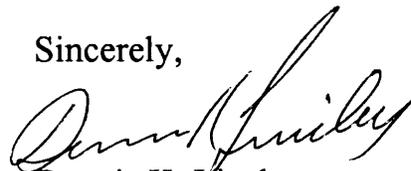
Packaging CCPs to control histamine formation listed in your HACCP plan for histamine forming fish for products processed on several occasions from January to June this year.

3. You must have sanitation control records that document monitoring and corrections during processing, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for products processed after March 9, 2000.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies at your firm. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. 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. Regulatory action may include seizure and/or injunction.

Please advise us in writing, within fifteen working days of receipt of this letter, of 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,



Dennis K. Linsley

Director

San Francisco District