



DEPARTMENT OF HEALTH & HUMAN SERVICES

41298d
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

May 21, 2001

Our Reference: 2920554

Carmelo J. Tringali, President
Monterey Fish Company, Inc.
840 Fir Avenue
Sand City, California 93955

WARNING LETTER

Dear Mr. Tringali:

On April 23, 2001, we inspected your seafood processing facility located at Municipal Wharf #2, Monterey, California. We conducted this inspection to determine your compliance with FDA's seafood processing regulations (21 CFR 123) and the current Good Manufacturing Practice (cGMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP and GMP deficiencies. The deficiencies cause your histamine forming fish such as Mahi-mahi, tuna, and Escolar 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.¹ We listed the deficiencies on a Form FDA 483 and discussed them with Salvatore P. Tringali, Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious deficiencies 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).
 - a) However, your firm's HACCP plan for **Fresh Mahi-mahi, Tuna, and Escolar**, lists critical limits at the receiving critical control

point (CCP) that are not adequate to control histamine formation as a result of time/temperature abuse during transport of fish received from other wholesalers. We wish to remind you that since your firm's HACCP plan lists monitoring of internal temperature and off odors as a control for histamine formation, you must maintain adequate records documenting these activities. For example, your firm received tuna, Mahi-mahi and Escolar from [REDACTED] on March 21, 2001, but did not record the receiving temperature and results of sensory examination.

- b) However, your firm's HACCP plan for **Frozen Tuna** lists critical limits at the receiving CCP that are not adequate to control histamine formation as a result of time/temperature abuse in tuna received directly from the harvest vessel.

To address the deficiencies cited above, Chapter 7 of the Fish & Fishery Products Hazards and Controls Guide can help provide the necessary guidelines.

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 plan for **Fresh Mahi-mahi, Tuna, and Escolar** does not list the critical control point of Cooler Storage for controlling the food safety hazard of histamine formation. We note that your HACCP plan lists a method of storage for the finished product to be iced and stored in a cooler at a temperature less than 45°F. A temperature of 40°F or less is recommended for maintaining safety of the product.
3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor processing conditions and employee practices with sufficient frequency to ensure the protection of food from contamination. Specifically, during the inspection, we found ice was held directly on the concrete floor of the ice bin.
4. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not have records to document monitoring of pest control at your facility.

In conjunction with the inspection, we collected and tested a sample of Mahi-mahi. Our analysis found the fish decomposed. Fish is adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, if it is entirely or partially decomposed. Your product must not be adulterated and they must be manufactured under current Good Manufacturing Practices.

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.

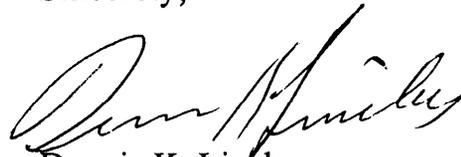
Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Your response should outline the specific things you are doing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

We acknowledge Mr. Salvatore M. Tringali's, HACCP Coordinator, response of May 1, 2001 to the inspectional observations presented to Mr. Salvatore P. Tringali at the close of the inspection. His reply has been appended to your company file. We will verify the corrections mentioned in his letter at the next inspection.

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,



Dennis K. Linsley

Director

San Francisco District

Enclosure

cc: Mr. Salvatore P. Tringali, Manager