



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

Our Reference: 2953643

November 27, 2001

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

WARNING LETTER

Dear Mr. Tringali:

On August 31, 2001, we inspected your seafood processing facility, located at 1222 Merrill Street, Salinas, California and found that you have a serious deviation from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). This deviation causes your canned mackerel, frozen mackerel, canned sardines, and frozen sardines 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, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov. See attached handout on how you can obtain a copy of the *FDA Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001*.

Your serious HACCP deviation is, as follows:

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 plans for canned mackerel, frozen mackerel, canned sardines, and frozen sardines lists critical limits at the receiving critical control point, as follows:

- Temperature less than 45°F:
This critical limit is not adequate to control the food safety hazard of histamine formation at receipt by the primary processor, as the temperature of the fish should be controlled at 40°F or less.

- No off odors:
This critical limit is not adequate because it does not specify a maximum and/or minimum value to which histamine formation can be controlled at the receiving critical control point. An adequate critical limit includes the number of off odor fish allowable per incoming lot (e.g., no more than 3 fish in a sample of 118 fish may show signs of decomposition).
- Caught within last 24 hours and iced:
This critical limit is not adequate to control histamine formation because it does not specify that the incoming fish was held at 40°F or less while in the custody of the harvest vessel.

Please refer to Chapter 7, Step #14, "For receipt by primary (first) processor," in the *FDA Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001*. A copy of Chapter 7 is enclosed for your ready reference.

We observed HACCP deviations during FDA inspection of your facility in August 1998. We reported the deviations to you, by correspondence from this office, on November 18, 1998. Your firm responded on December 18, 1998. Your response, however, was in general terms. We did not have the opportunity to review your actual HACCP plans.

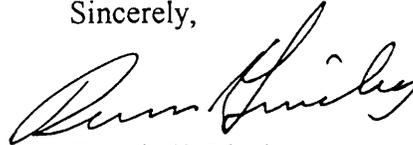
At the conclusion of the August 2001 inspection, the deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with you. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. You are responsible for ensuring that your processing facility operates in compliance with the Act, the Seafood HACCP regulations, the Good Manufacturing Practice regulations (21 CFR 110), and, where applicable, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers regulations (21 CFR 113).

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation 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 deviations.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosure:

Form FDA 483

Handout on *FDA Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.*

Chapter 7 of *FDA Fish & Fisheries Products Hazards & Controls Guidance, 3rd edition, June 2001.*