



DEPARTMENT OF HEALTH AND HUMAN SERVICES

94825d

Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2445

Telephone: 949-608-2900
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WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

June 24, 2004

W/L 40-04

Miki D. Koleiopu, President
Million Food Corp. dba Top Seafood Company
535 South Standard Avenue
Los Angeles, California 90013

Dear Ms. Koleiopu:

We inspected your seafood processing facility, located at 535 South Stanford Ave., Los Angeles, California, 90013 on April 2-7, 2004 and found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations Part 123 (21 CFR Part 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342(a)(4). Accordingly, your refrigerated fresh tuna and salmon fillets are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a), and (b). However your firm does not have a HACCP plan for raw, refrigerated tuna fillets intended for raw consumption by the consumer to control the food safety hazards of histamine formation and pathogen growth. In addition, your firm does not have a HACCP plan for raw refrigerated salmon intended for raw consumption to control the food safety hazard of pathogen growth.

Please note that the hazard of parasite survival for your sashimi grade salmon that is intended to be consumed raw may also be a hazard that is reasonably likely to occur in your process if you receive salmon that is wild-caught and not commercially frozen prior to receipt. Your hazard analysis should determine whether this hazard is reasonably likely to occur for your current operations.

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor and correct problems in sanitation in the following areas:

Condition and Cleanliness of Food Contact Surfaces (21 CFR 123.11(b)(2)):

- A buildup of residue was observed along the walls of a stainless steel ice bed used to hold in-process fresh sashimi grade tuna fillets and fresh sashimi grade salmon fillets. Tuna fillets were observed in direct contact with these walls.
- The cutting board in the processing room used to fillet fresh sashimi grade tuna and fresh sashimi grade salmon was observed with numerous grooves preventing adequate cleaning and sanitation.

Prevention of Cross-Contamination from Insanitary Objects (21 CFR 123.11(b)(3)):

- Five employees did not wash their hands upon returning to the processing room after exiting the building. These employees were observed handling fresh sashimi grade tuna fillets and fresh sashimi grade salmon fillets upon their return.
- Two fresh sashimi grade salmon fillets awaiting packaging were observed in direct contact with a wall that had a buildup of residue. This wall was not cleaned during post-operational cleaning, and there is no pre-operational cleaning.
- A large fresh sashimi grade tuna was observed being held on a piece of Styrofoam that spanned across the opening of a trash can holding inedible fish parts. Splatter in various directions from the disposal of inedible fish parts into an adjacent trash can was observed.

Maintenance of Hand Washing, Hand Sanitizing, and Toilet Facilities (21 CFR 123.11(b)(4)):

- Lack of paper towels or a suitable hand-drying device was observed in the only employee restroom.
- Lack of paper towels was observed at the only hand wash sink in the processing room.

Proper Labeling, Storage and Use of Toxic Chemicals (21 CFR 123.11(b)(6)):

- A pail of cleaning detergent was observed stored in the walk-in cooler next to stacked cases of amberjack and Kampachi, a pail of salted ginger, and on top of a container of salted herring roe.

Exclusion of Pests (21 CFR 123.11(b)(8)):

- Two fly-like insects were observed in the processing room.
 - Seven fly-like insects were observed in the vestibule into the processing room. The door from the vestibule to the processing room was frequently opened throughout the day and was observed propped open at the start of the inspection.
3. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However your firm did not maintain any sanitation monitoring records.
 4. You must perform ongoing verification activities such as the calibration of process-monitoring instruments, to comply with 21 CFR 123.8 (a)(2)(ii). However, your temperature indicators for the walk-in cooler are not accurate. On 4/02/04, the following was observed:
 - The temperature indicator in the walk-in cooler read [REDACTED] however, a calibrated FDA thermometer read +36°F.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response copies of documentation such as HACCP plans, monitoring forms and recent monitoring data 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 deviations.

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 (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

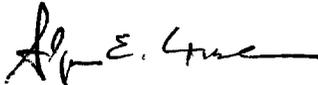
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Your written reply should be addressed to:

Pamela B. Schweikert
Director, Compliance Branch
U. S. Food and Drug Administration
19701 Fairchild
Irvine, California 92612-2445

If you have any questions regarding this letter please contact Mr. Robert B. McNab, Compliance Officer at (949) 608-4409.

Sincerely,



Alonza E. Cruse
District Director

Cc: Mr. Yoshi Mae, General Manager
535 Standford Avenue
Los Angeles, CA 90013