



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

NOV 2 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Myung Kyu Lee, President
Quality Fresh Fish Express
624 Gladys Avenue
Los Angeles, CA 90021

W/L # 06-00

Dear Mr. Lee:

On June 3, 1999, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of Quality Fresh Fish Express, located at the above address. At the conclusion of the inspection, you were presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products Regulation. By virtue of these deficiencies, the tuna products processed at your facility are adulterated within the meaning of Section 402 (a) (4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found the following deficiencies, related to filleted tuna, intended for raw consumption, and stored and sold as a refrigerated product:

1. The HACCP plan created by your firm is inadequate to address the hazards associated with fresh tuna, per 123.6(c)(2)(i). Specifically, your plan addresses only one critical control point (CCP), namely "Receiving." Your firm has not addressed the hazards of histamine formation in the tuna during processing and storage, and these steps are not identified as CCPs in your HACCP plan for fresh tuna. Your firm must assure that the tuna you process and store does not form histamine due to time-temperature abuse. Appropriate CCPs must be developed by your firm to address all relevant hazards, with appropriate critical limits, monitoring procedures, recordkeeping and verification procedures.

2. The HACCP plan created by your firm for fresh tuna has not been implemented as required under 21 CFR 123.6(b). Monitoring procedures, and other procedures stated in your HACCP plan are not being followed and documented.
3. Your HACCP plan does not meet the requirements of 21 CFR 123.6(c) in the following ways.

- A. Your plan specifies that all lots received must be accompanied by transportation records that show that the product was maintained at or below [REDACTED] throughout transit. However, the procedures and frequency of monitoring (21 CFR 123.6(c)(4)) are not listed in your plan. In addition, there are no verification procedures or record keeping provisions (21 CFR 123.6(c)(6-7)).

For fish that are held under ice or a chemical medium, your plan specifies monitoring of the adequacy of ice. However, the frequency of monitoring listed pertains to in-process or finished product refrigeration not product at receipt.

Your plan should provide for checking the adequacy of cooling medium for every lot that depends on a cooling medium for maintaining temperatures below [REDACTED].

Likewise, your plan must provide for the frequency of monitoring of internal temperature of refrigerated fish at receipt and it does not. Please specify what type of record you will use e.g. receiving log book.

- B. Your corrective action indicates only to "Add ice". This corrective action has not been developed in accordance with 21 CFR 123.7(b). This corrective action shall ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation (i.e. hold and evaluate product); and the cause of the deviation is corrected.
 - C. Your verification procedures as written do not include monitoring and/or corrective action record review. 21 CFR 123.6(c)(6) requires that you list the verification procedures and frequency thereof, that the processor will use in accordance with 21 CFR 123.8(a), i.e. reassessment of the HACCP plan, ongoing verification activities, and records review.
4. Your HACCP plan does not include required information per 21 CFR 123.9(a). All records required by 21 CFR 123 shall include the following information: (1) the name and location of the processor; (2) the date and time of the activity that the record reflects; (3) the signature or initials of the person performing the operation; and (4) where appropriate, the identity of the product and the production code, if any. This HACCP plan was also not signed and dated as required by 21 CFR 123.6(d).

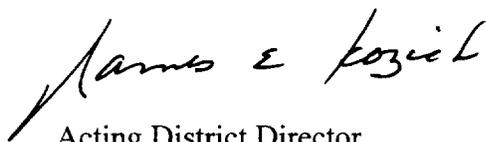
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice, such as seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your written reply should be directed to:

Thomas L. Sawyer, Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

Sincerely,



Acting District Director

cc: California Department of Health Services, Food & Drug Branch
601 N. 7th Street
Sacramento, California 94234-7320
Attn: Stuart Richardson, Jr., Chief