



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

1990 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

July 2, 2003

Ms. Supatra Bovornsivamon, President
LAX-C Inc.
1100 N Main Street
Los Angeles, CA 90012

W/L 43-03

Dear Ms. Bovornsivamon:

On April 18 & 21, 2003, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 1100 N Main Street, Los Angeles, CA 90012. The inspection was conducted to determine your firm's compliance with Title 21 of the Code of Federal Regulations Part 123 (21 CFR §123).

During our inspection, the FDA investigator observed that your firm did not comply with importer verification requirements. This serious deviation has caused the frozen mackerel imported by your firm to be adulterated within the meaning of Section 402 (a)(4) of the Food, Drug, and Cosmetic Act (the Act), in that you failed to provide verification per 21 CFR 123.12 (d) that your fish and fishery products have been processed under conditions that comply with requirements of 21 CFR 123. The FDA investigator provided you with an FDA 483 listing these serious deviations:

- (1) You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for frozen mackerel imported from [REDACTED]
- (2) You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen mackerel manufactured by [REDACTED] in [REDACTED].

Similar deviations were noted at your firm at the previous inspection on July 25, 2001.

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Your product specifications document dated May 2, 2003 was received, and it does address the first observation identified above. However, the second observation of providing an affirmative step is needed to comply with the mentioned seafood HACCP regulations.

The above-identified deviations are not intended to be an all inclusive list of deficiencies at your facilities. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

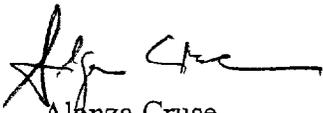
Your written reply relating to these concerns should be directed to:

U.S. Food & Drug Administration
Attn: Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

If you have questions regarding the implementation of the HACCP Regulations, you may contact Ruth P. Dixon, Compliance Officer, at (310) 831-6123 extension #155 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,



Alonza Cruse
District Director