



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

VIA FEDERAL EXPRESS

Our Reference: 3003475203

August 30, 2004

David S. Ly, Owner
David S. Ly dba TV Food Co.
2964 Alvarado Street, Suite E
San Leandro, California 94577-5725

WARNING LETTER

Dear Mr. Ly:

On April 7, 12, 13, and 19, 2004, the U.S. Food and Drug Administration (FDA) inspected your facility, located at 2964 Alvarado Street, San Leandro, California. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 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). Accordingly your imported clams or clam meat, blood cockles, and frozen mackerel from [REDACTED] 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 may find the Act and the seafood HACCP Regulation through links in FDA's home page at www.fda.gov.

During the previous inspection of your firm on January 21, 2003, the FDA Investigator issued you a Form FDA 483 which included observations that your firm did not have product safety specifications or written verification procedures completed for all seafood products imported by your firm, specifically Mackerel. To date FDA has not received corrections to these observations. Additionally the following deviations were observed during the latest inspection of your firm.

The deviations were as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated because they may be injurious to

health or have been processed under insanitary conditions, to comply with 21 CFR 123.12(a) (2)(i). However your firm does not have product specifications for the clams, blood cockles, and frozen mackerel that you import into the United States from [REDACTED]. Your product specifications should address and set limits for safety hazards associated with the products you import.

Please be aware that [REDACTED] does not have a Memorandum of Understanding for molluscan shellfish with the United States. Therefore raw molluscan shellfish, such as blood cockles and clams or clam meat, imported from this country can be subject to embargo by the local state shellfish authority upon entry.

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, either your firm did not perform an affirmative step or your firm did not perform a complete affirmative step for the clams, blood cockles, and frozen mackerel that you import into the United States from [REDACTED]. Your firm appears to have chosen to maintain HACCP plans for the products you import. However, you have failed to maintain a HACCP plan and letter of guarantee for clams, blood cockles, and frozen mackerel. We have enclosed a copy of 21 CFR 123 for your ready reference. See 21 CFR 123.12 for requirements for imported products.

At the conclusion of the inspection, the observed deviations were listed on Form FDA 483 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 regulation, and the Current Good Manufacturing Practice regulation (21 CFR 110).

We may take further action if you do not promptly correct these violations. 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.

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 these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections.

Please send your reply 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,



Barbara J. Cassens
District Director
San Francisco District

Enclosures:

Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)
Form FDA 483