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VIA FEDERAL EXPRESS

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Our Reference: 2953895

Leo K. Vu, President
Vu Family Corporation
Pier 28, The Embarcadero
San Francisco, California 94105

WARNING LETTER

Dear Mr. Vu:

On March 3, 4, 5, and 8, 1999, a team of U.S. Food and Drug Administration (FDA) investigators, FDA chemist, and State of California Department of Health Services Food and Drug Branch (CAFDB) investigator conducted an inspection of your seafood processing facility, Sea Win Fish Company located at Pier 28, The Embarcadero, San Francisco, California. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). In conjunction with the inspection, FDA collected and analyzed samples of cooked whole crab, cooked crab legs, and cooked crab sections and a sample of albacore tuna. Results of those analyses revealed that these products are violative, as follows:

<u>Product</u>	<u>Sample Number</u>	<u>Findings</u>
Cooked Whole Crab	41142	13 of 13 subs decomposed indole analysis: 5 of 6 subs greater than 25ug/100 g
Cooked Crab Legs	41143	14 of 14 subs decomposed
Cooked Whole Crab	41144	17 of 17 subs decomposed
Albacore Tuna	41145	17 of 17 subs decomposed

The lots of crab and tuna are deemed to be adulterated within the meaning of Section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act, in that they are in whole or in part decomposed. These decomposed crabs and tuna were ultimately voluntarily destroyed during the inspection.

During the inspection, the investigators observed gross insanitary conditions which constitute violations of the Federal Food, Drug, and Cosmetic Act and related regulations for good manufacturing practices (GMPs), which are established in Title 21, *Code of Federal Regulations*, Part 110. The investigators also observed shortcomings in your HACCP system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The GMP violations and HACCP deviations were listed on Form FDA 483, and discussed with you.

The GMP violations included the following:

1. Failure to have effective quality control operations to ensure that food is fit for human consumption (21 CFR 110.80)). Organoleptic examination of frozen whole tuna, revealed that 15 fish were decomposed. These fish were stored in your freezer. You told the investigators that all products held at your facility are for distribution.
2. Failure to provide adequate screening or other protection against pests at your plant to protect food from any source of contamination (21 CFR 110.20(b)(7) and 21 CFR 110.35(c)). Several one-foot gaps were observed along the wall to the outside wharf; there is no door or complete wall to separate the facility from other facilities outside the warehouse. Rodent activities were observed in the cooler and in the processing area. A pigeon was also observed flying in the facility on March 2, 1999.
3. Failure to clean and sanitize utensils and food contact surfaces (21 CFR 110.35(a) and (d)).
4. Failure to provide a water supply that is safe and of adequate sanitary quality for holding live crabs (21 CFR 110.37(a)). During the inspection, the investigators observed that live crabs were stored in San Francisco Bay water, a non-potable water supply.
5. Failure to provide adequate floor drainage in the processing area (21 CFR 110.37(b)(4)). During the inspection, the investigators observed pools of standing water approximately two feet from the ice machine and approximately three feet from the live crab tank.

6. Failure to have backflow prevention devices in waterline pipes leading to the live crab tank (21 CFR 110.37(5)).
7. Failure to have readily accessible and sanitary toilet facilities (21 CFR 110.37(d)). The nearest toilet facility, located about thirty feet away from your facility, is not being maintained in a sanitary condition and does not appear to be working.
8. Failure to have any handwashing and hand sanitizing facilities in the plant (21 CFR 110.37(e)).
9. The ice machine reservoir is unprotected; ice chute is rusty; and the shovels used to scoop ice for cooked whole crabs are dirty. Furthermore, the barrier at the entrance of the ice room (to prevent ice overflow) is made of wood, and splintered, which make cleaning difficult (21 CFR 110.40(a)).
10. Employees were observed with no hair restraints while packing live crabs for distribution (21 CFR 110.10(b)(6)).

Because of these GMP violations, foods in your facility may be adulterated within the meaning of Section 402(a)(4) in that they were prepared, packed, or held under insanitary conditions whereby they may become contaminated with filth, or whereby they may be rendered injurious to health.

Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Section 301(c) prohibits the receipt in interstate commerce of any food that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise. The adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k). Section 302 authorizes the government to seek injunctive relief to restrain violations of Section 301 of the Act.

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

In addition to the violations mentioned above, we bring the following HACCP deviations to your attention. The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrate to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been operating HACCP systems advise us that they benefit from them in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, the investigators observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The investigators also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 (Inspectional Observations), which present their evaluation of your firm's performance regarding various aspects of the HACCP. The observations of concern to us are as follows:

1. Failure to develop and implement a written HACCP plan to address potential food safety hazards associated with crabs received and processed at your firm (21 CFR 123.6(b)).
2. Failure to develop and implement a written HACCP plan to address food safety hazards associated with fresh albacore tuna received and processed at your firm (21 CFR 123.6(b)).
3. Failure to maintain sanitation control records that document the monitoring and corrections of sanitation conditions and practices during processing (21 CFR 123.11(c)).
4. Failure to monitor sanitation conditions and practices at your firm during processing (21 CFR 123.11(b)).

The investigators also reported a deficiency related to the handling and processing of raw molluscan shellfish at your firm. This observation will require your immediate attention and follow-up action. Regulatory follow-up on the deficiency will be conducted by the State Shellfish Control Authority, who is responsible for molluscan shellfish sanitation in California. Your firm failed to develop and implement a written HACCP plan to address

potential food safety hazards associated with fresh and frozen molluscan shellfish received and stored at your facility.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's assessment, you should explain how your system is complying with the seafood HACCP regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

In either case, you should respond to this office concerning the HACCP deviations within thirty working days of the receipt of this letter. Upon receipt of your response, we will work with you to resolve any outstanding issues associated with your HACCP system.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Erlinda Figueroa, Compliance Officer (Telephone: 510-337-6795; Fax: 510-337-6707). If you have questions regarding the implementation of the HACCP regulation, you may contact Ms. Darla Bracy, Investigator, at (510) 337-6773 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,



Patricia C. Ziobro
District Director
San Francisco District