



DEPARTMENT OF HEALTH & HUMAN SERVICES

94550d

Public Health Service
Food and Drug Administration
Los Angeles District

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

WARNING LETTER

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Mr. Nam Tran, President
Sea Win, Inc.
617 S. Stanford Ave.
Los Angeles, CA 90021

February 24, 2004

W/L: 28-04

Dear Mr. Tran:

On January 13, 2004, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 617 S. Stanford Ave., Los Angeles, CA. The inspection was conducted to determine your firm's compliance with the Fish and Fishery Products regulations, Title 21 of the Code of Federal Regulations Part 123 (21 CFR § 123).

The Fish and Fishery Products regulations, which became effective on December 18, 1997, require that as an importer you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as a Hazard Analysis Critical Control Point (HACCP) plan in accordance with U.S. requirements. Failure of a processor, foreign or domestic, to have and implement a HACCP plan that complies with the requirements 21 CFR § 123, 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)). You may find the Act and the Fish and Fishery Products regulations through links in FDA's home page at www.fda.gov.

During our inspection, the FDA investigator observed serious deviations in your seafood HACCP program as an importer, including failure to comply with the importer verification requirements listed in the Fish and Fishery Products regulations, Section 123.12, "Special Requirements for Imported Products." The FDA investigator also provided you with a copy of the FDA 483, Inspectional Observations, which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. Accordingly, your frozen king mackerel and frozen shrimp are adulterated in that the products 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.

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

This inspection was also a follow-up to previous inspections conducted on June 21, 2000, and February 18-19, 2003, to verify that corrective actions had taken place for frozen king mackerel and frozen shrimp that you had previously imported, and subsequent entries of these products. A copy of the FDA 483 was also given to you as a result of those inspections. At the most recent inspection, you informed the investigator that you had not made any of the corrective actions for the frozen king mackerel and frozen shrimp.

The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. 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 its implementing federal regulations.

You should take prompt measures to correct these deviations from the Fish and Fishery Products regulations. Failure to promptly do so may result in regulatory action without further notice. Such action may include seizure and/or injunction. FDA may also detain your seafood products without examination.

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 fifteen (15) working days, state the reason for the delay and the time frame within which the corrections will be completed.

Letter to Mr. Tran

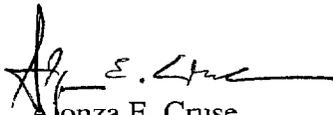
Page 3

Your written reply should be directed to:

U.S. Food & Drug Administration
Attn: John L. Stevens
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 Fish and Fishery Products regulations, you may contact Ruth P. Dixon, Compliance Officer, at (310) 971-2299.

Sincerely,



Alfonza E. Cruse
District Director