



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

April 5, 2001

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 35-01

Nam T. Tran, President
Sea Win, Inc. (doing business as Best Seafood Co.)
526 Stanford Avenue
Los Angeles, California 90021

Dear Mr. Tran:

We inspected your firm, located at 526 Stanford Avenue, Los Angeles, California, on January 17-19 & 31, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123) and the Current Good Manufacturing Practice regulations (21 CFR Part 110). These deviations, some of which were previously brought to your attention, cause your ready-to-eat, vacuum-packaged, cooked sea cucumber products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the applicable regulations through links in FDA's home page at www.fda.gov.

For your **domestic processing** operations, the deviations were as follows:

1. You must have a written HACCP plan that lists the food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(c)(1). However, your HACCP plan for ready-to-eat sea cucumbers does not list the food safety hazards of pathogen survival through cooking, pathogen growth and toxin formation due to time/temperature abuse during cooling/cleaning, and *Clostridium botulinum* growth during finished product storage.

Your HACCP plan currently lists the food safety hazard of "Natural Toxins" for each of your critical control points, "Receiving", "Processing", and "Storage (Freezer)". Natural toxins are not food safety hazards that are reasonably likely to occur with sea cucumbers.

In addition, it appears that temperature control is the sole barrier for *Clostridium botulinum* growth and toxin formation in your vacuum-packaged ready-to-eat sea cucumber products. Therefore, these products should be labeled to kept frozen and to be thawed under refrigeration immediately before use, or to break the vacuum seal (e.g., important, keep frozen until used, thaw under refrigeration; or vacuum seal must be broken when thawed).

2. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11 (b). However, your firm did not monitor your processing facility adequately, as evidenced by the serious sanitation deficiencies noted during the January, 2001 inspection. These conditions included:
 - a) An employee was observed eating in-process (cooked – prior to packaging) sea cucumbers during the inspection, then handling in-process product without cleaning and sanitizing the bare hands.
 - b) Employees were observed not cleaning and sanitizing their hands when returning to the processing room whereon they were observed handling in-process product after cooking and prior to the packaging step.
 - c) Food contact surfaces, including equipment and hands are not being sanitized as necessary, as evidenced by a lack of sanitizing agent in the processing plant.
 - d) Processing hoses were observed lying on the dirty processing room floor. These hoses are handled by processing employees that handle in-process sea cucumbers after cooking and prior to the packaging step.

Each of these sanitation conditions can affect the safety of your ready-to-eat sea cucumber products. 21 CFR 123.6(f) states that sanitation controls do not need to be included in a HACCP plan, provided that they are monitored in accordance with the sanitation monitoring requirements of the regulation [21 CFR 123.11(b)]. However, in light of the deficiencies noted above, your firm may wish to create critical control points for prevention of cross-contamination [i.e. handling and storage of post-cooked products prior to packaging]; condition and cleanliness of food contact surfaces; and maintenance of hand washing and hand sanitizing facilities.

For your **import** operations, 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 injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for sea cucumbers imported from Taiwan.
2. You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm does not have any affirmative step documented to show that the firm foreign processor has processed the sea cucumbers in accordance with the seafood HACCP regulations. Thus you cannot assure yourself that the HACCP plan that the processor uses properly addresses food safety hazards that are reasonably likely to occur for the fish or fishery product they process, and that this plan is being properly implemented.

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. With regard to your importation of fisheries products, failure to correct deficiencies above related to importation may result in refusal of admission pursuant to Section 801(a)(1) of the Act. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations (21 CFR Part 123), and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Product Labeling:

A review of your finished product labels for "White Seacucumber" and "Black Seacucumber" reveals that your products are considered misbranded within the meaning of Section 403 of the Act, and the Food Labeling Regulations (21 CFR 101). The labeling deviations are as follows:

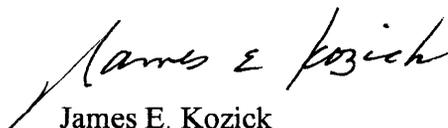
1. Failure to include the net weight statement, as required under section 403(e)(2) of the Act, and 21 CFR 101.105.

The above-cited labeling violations are not intended to be an all-inclusive statement of the deficiencies that may exist with your finished product labels. It is your responsibility to ensure that all of your products are labeled in compliance with the requirements of the Act, and the Food Labeling regulations as appropriate. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure.

Please notify this office in writing, within 15 working days from your receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. You may wish to include in your response documentation such as written HACCP plan(s) for your domestic operations, and importer verification steps including product specifications and complete affirmative steps, revised product labels, or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed before you respond, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions relating to this letter you should contact Robert B. McNab, Compliance Officer, at (949) 798-7709. Your written reply should be directed to Mr. Thomas L. Sawyer, Director, Compliance Branch, U.S. Food & Drug Administration, 19900 MacArthur Blvd, Suite 300, Irvine, CA 92612-2445.

Sincerely,



James E. Kozick
Acting District Director
Los Angeles District