



WARNING LETTER

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 1, 2003

W/L 33-03

Mr. Glen K. Kuba, President
Leong-Kuba Sea Products, Inc.
6230 Marindustry Drive
San Diego, CA 92121

Dear Mr. Kuba:

On February 11-12, 2003, we inspected your seafood processing facility, located in San Diego, California. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, 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), 21 U.S.C § 342(a)(4). Accordingly your ready-to-eat sashimi grade tuna and yellowtail are adulterated, in that the fresh fishes 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 Regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must maintain sanitation control records that, at a minimum, document monitoring and corrections, to comply with 21 CFR 123.11(c). However your firm could not provide any monitoring records for the monitoring of the safety of water; the condition and cleanliness of food contact surfaces; the prevention of cross-contamination from insanitary objects to food; the maintenance of hand washing and hand sanitizing facilities; the protection of food from chemical contaminants; the proper labeling and use of toxic compounds; the control of employee health conditions; and the exclusion of pests from October 2002 to present. In addition, the forms that you used in October 2002 and previous months lacked all necessary monitoring elements except for monitoring the maintenance of hand washing, hand sanitizing, and toilet facilities. This lack of sanitation monitoring has been previously brought to your attention, most recently during the 2/22-23/01 inspection and the corresponding 4/05/01 letter sent to your firm by FDA outlining your HACCP and GMP deficiencies.

Letter to Mr. Kuba, Leong-Kuba Sea Products, Inc.

Page 2

2. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor one or more of the eight areas of sanitation with sufficient frequency to ensure control as evidenced by:
 - Fillet knives were observed being stored in crevices between filleting tables/cutting boards between uses. (Failure to prevent cross contamination.)
 - There were no soap and sanitizing solutions at the hand wash station. (Failure to monitor hand-washing facilities.)

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should include each step that has been taken to completely correct the current violations and to prevent the recurrence of similar violations, the time within which correction will be completed, and any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, please explain the reason for your delay and state when you will correct any remaining deviations.

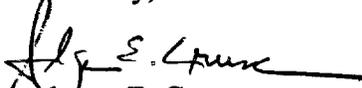
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP Regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be directed to:

Director, Compliance Branch
U.S. Food & Drug Administration
19900 MacArthur Blvd, Suite 300
Irvine, CA 92612-2445.

If you have questions regarding any issue in this letter, please contact Mr. Robert B. McNab, Compliance Officer at (949) 798-7709.

Sincerely,


Alonza E. Cruse
District Director