



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
g380sd

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

WARNING LETTER

January 15, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

W/L 17-03

Libia J. Melendez
Pacific Blue Seafood Company
152 South Mission Road
Los Angeles, CA 90033

Dear Ms. Melendez:

On September 25th – 27th and October 3rd 2002, we inspected your seafood processing facility, located in 152 South Mission Road, Los Angeles, CA 90033. We found that you have a serious deviation from the seafood 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), 21 U.S.C § 342(a)(4). Accordingly your **scombroid-forming fishes** are adulterated, in that these 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 regulation through links in FDA's home page at www.fda.gov.

The deviation is as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as a "point, step, or procedure in a food process at which control can be applied, and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." Your firm's HACCP plan for fresh tuna does not list the critical control point of Refrigerated Storage to control pathogen growth (thus controlling histamine formation) during the storage of raw materials and finished product.

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We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct the deviation.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation such as copies of your updated HACCP plan for fresh tuna or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

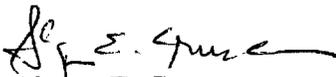
This letter may not list all of the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use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

If you have any questions regarding the seafood HACCP regulation or how to develop or implement a HACCP plan in your facility, you may contact Mr. Robert B. McNab, Compliance Officer at 949-798-7709.

Your written reply should be directed to:

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

Sincerely,



Alonza E. Cruse
District Director
Los Angeles District