



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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WARNING LETTER

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

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

March 15, 2002

WL-32-02

Mr. Nicholas V. Vitalich, Owner/President  
Catalina Fish Company  
2210 Signal Place  
San Pedro, California 90731

Dear Mr. Vitalich:

On January 23-25, 2002, an Investigator from the Food & Drug Administration (FDA) conducted an inspection of Catalina Fish Company, located at the above address. At the conclusion of the inspection, you were presented with Form FDA 483 listing significant deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products Regulation. By reason of these deficiencies, the fisheries products processed at your facility are adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found the following deficiencies, related to fresh histamine-forming fishes such as albacore tuna and yellowtail and mackerel received, stored and sold as refrigerated products:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan to control the food safety hazard of histamine formation in your fresh histamine-forming fishes that you receive from harvesting vessels as well as from secondary processors via delivery truck.

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.

In addition to the violations noted above, we offer the following comments regarding your firm's seafood processing:

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- A. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor exclusion of pests from the food plant with sufficient frequency to ensure control as evidenced by: Strip curtains at both doorways of the processing facility were tied back which can allow insects and other vermin to freely enter the facility, and no other barriers to vermin entry were in place. In addition, several flying insects were observed flying in the processing room.
- B. You must have sanitation control records that document monitoring and corrections, in order to comply with 21 CFR 123.11(c). However, your firm does not have any of these records.

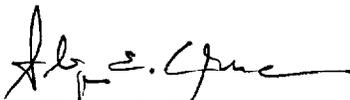
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures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

This matter has been assigned to Compliance Officer Robert McNab; any specific questions you may have may be directed to him at phone number 949-798-7709.

Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch  
U. S. Food and Drug Administration  
19900 MacArthur Boulevard, Suite 300  
Irvine, California 92612-2445

Sincerely,



Aloha E. Cruse  
District Director