



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

32511

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

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

**WARNING LETTER**

July 13, 2001

WL-66-01

Thomas G. Moore, Owner  
Ocean Pride Seafood  
2894 Bunsen Avenue, Unit B  
Ventura, CA 93003

Dear Mr. Moore:

We inspected your firm, located at 2894 Bunsen Avenue, Unit B, Ventura, CA on March 10 & 11, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh tuna, yellowtail and escolar to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

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 for fresh tuna, fresh yellowtail, fresh escolar and/or other histamine-forming fishes to control the food safety hazard of scombrototoxin (histamine) at receipt or formation during processing and/or storage.

We are especially concerned because the need for such a HACCP plan was brought to your attention by our investigators during each of the past two inspections, including the September 30, 1999 inspection and the June 29, 2000 inspection. This deficiency was brought to your attention during discussions and on the form FDA-483 presented to you during the close of these inspections. In fact, it appeared during the June 2000 inspection that you had developed a HACCP plan to address this food safety hazard during the course of the inspection.

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.

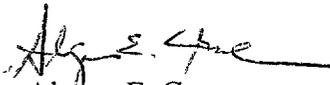
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to

include in your response documentation such as your HACCP plan and copies of any HACCP monitoring records that you have implemented, 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 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.

Please send your reply to the Food and Drug Administration, Attention: 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 Robert McNab, Compliance Officer at (949) 798-7709.

Sincerely,

  
Alonza E. Cruse  
District Director