



DEPARTMENT OF HEALTH AND HUMAN SERVICE

944/d

Food and Drug Administration  
New Orleans District  
Southeast Region  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

Telephone: 504-253-4519  
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November 25, 2003

**WARNING LETTER NO. 2004-NOL-06**

**FEDERAL EXPRESS  
OVERNIGHT DELIVERY**

Mr. Steven V. Le, President  
Steven Seafood Inc.  
8893 Shrimpers Row  
Dulac, Louisiana 70353-2213

Dear Mr. Le:

We inspected your firm, located at 8893 Shrimpers Row, Dulac, Louisiana, on October 17, 22 &– 24, 2003, and found that you have serious deviations from Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations, some of which were previously brought to your attention, cause your fresh tuna, mahi-mahi, swordfish, wahoo, and oilfish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the Seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for tuna and mahi-mahi does not list the critical control point of storage for controlling the food safety hazard of histamine formation.
- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for tuna and mahi-mahi does not list critical limits for sensory and internal temperature examinations at the receiving critical control point to control histamine formation.
- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not maintain vessel harvest records at the fish receiving critical control point to control histamine formation as listed in your HACCP plan for tuna and mahi-mahi.

In addition, the investigator documented numerous insanitary conditions that cause the fish to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations were as follows:

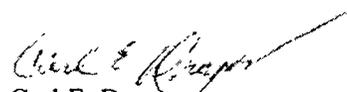
- Your firm did not monitor adequately the conditions and cleanliness of food contact surfaces as required by 21 CFR 123.11(b)(2). This omission further violates the requirements of 21 CFR 110.35(d) in that your firm's food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example, on October 22, 2003, you used a conveyor belt with apparent bird droppings on it to transport tuna and swordfish. The conveyor was washed with only water prior to beginning the transport operations.
- Your firm did not monitor adequately the prevention of cross-contamination from insanitary objects to food as required by 21 CFR 123.11(b)(3). This omission further violates the requirements of 21 CFR 110.10(b)(9). Specifically, employees used two shovels that were resting directly on the floor to cover fresh fish with ice without washing or sanitizing the shovels. In addition, employees used a knife and thermometer that were not washed or sanitized before fish grading procedures.

We may take action without further notice if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating. We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your revised HACCP plan, vessel monitoring/histamine testing records and storage temperature records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

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 CGMP regulations. 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 U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the address above. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,

  
Carl E. Draper  
District Director  
New Orleans District

Enclosure: Form FDA 483