



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

Telephone: 504-253-4519
Facsimile: 504-253-4520

September 5, 2001

WARNING LETTER NO. 2001-NOL-54

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Steven H. Loga, President
Seafood Warehouse, Inc.
1501 Whitney Avenue
Gretna, Louisiana 70056

Dear Mr. Loga:

We inspected your firm, located at 1501 Whitney Avenue, Gretna, Louisiana, on July 18 and 20, 2001 and found that you have serious deviations from the 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 scombrototoxin forming fish and ready-to-eat crabmeat, boiled shrimp, boiled crabs, and boiled crawfish to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must have a 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 ready-to-eat crabmeat, boiled shrimp, boiled crabs, and boiled crawfish to control the food safety hazards of pathogen growth and toxin 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 follow the monitoring procedure of documenting the presence of ice and/or fish core temperature at the receiving critical control point as listed in your HACCP plan for fresh, raw Yellowfin Tuna, Mahi-Mahi, Wahoo, and Escolar. In addition, your firm did not follow the monitoring procedure of documenting the presence of ice and/or fish core temperature at the shipping critical control point as listed in the same HACCP plan. This deviation was previously brought to your attention in our letter of January 18, 2001.
- 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 fresh, raw Yellowfin Tuna, Mahi-Mahi, Wahoo,

and Escolar does not list the critical control point of processing for controlling the food safety hazard of scombrotoxin.

- 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 Amberjack, Pompano, Snapper, and Triggerfish listing the critical limit, i.e. presence of ice on the fish and odor of the fish, at the receiving critical control point is not adequate to control ciguatera fish poisoning.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the condition and cleanliness of food contact surfaces with sufficient frequency to ensure control as evidenced by:
 - (a) A processed fish storage rack encrusted with residue from previous operations; and
 - (b) Employees wearing aprons with black residue from previous operations.

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

The deviations were as follows:

- Our investigator observed conditions that facilitate unsanitary operations, which are associated with the construction and design of your facility. For example:
 - (a) Condensed water dripped from the ceiling directly onto processed fish; and
 - (b) A pest strip covered with flies hung from the ceiling directly above fresh fish.
- Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of those items from microorganisms or foreign substances. For example:
 - (a) An employee handled an unclean electric pallet jack and then proceeded to fillet fish without washing or sanitizing his gloved hands; and
 - (b) Employee's unclean clothing came in contact with processed fish.
- Your cleaning and sanitizing of utensils and equipment are not conducted in a manner that protects food and food contact surfaces from contamination. For example:
 - (a) Throughout the inspection, you did not have hand sanitizers in the processing room; and
 - (b) The bathrooms did not have paper towels.

We are aware that you revised your HACCP plan for fresh, raw Yellowfin Tuna, Mahi-Mahi, Wahoo, and Escolar to include the critical control point for storage and revised your receiving record during the inspection.

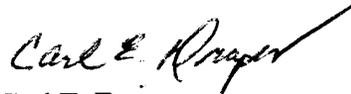
You should notify this office in writing, within 15 working days of receipt of this letter, of the specific actions you are taking to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. You may wish to include in your response documentation

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such as copies of temperature monitoring records, receiving and shipping records or other useful information that would assist us in evaluating your corrections. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Send your reply to the U.S. Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. 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