



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

**New York District**

93010d

Food & Drug Administration  
158-15 Liberty Avenue  
Jamaica, NY 11433

January 4, 2002

**WARNING LETTER**

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

Ref: NYK-2002-18

Mr. Anthony Mazzella  
President  
Tony Crab King, Inc.  
103 South Street  
New York, NY 10038

Dear Mr. Mazzella:

We inspected your seafood processing facility, located at 103 South Street, New York, New York on November 20, 2001 and December 6, 2001, and found that you have serious deviations from the Seafood HACCP regulations (Title 21, Code of Federal Regulations, Part 123 (21 CFR 123)). These deviations, cause your histamine producing (scombroid) fish 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 the links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations included, but are not limited to, the following:

1. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HAACP plan for histamine species does not include the frequency for monitoring the "display" critical control point and the individual(s) responsible for "display" monitoring.
2. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm does not follow the monitoring procedure for the "display" critical control point to control the histamine hazard listed in your HACCP plan for scombroid species, since your firm does not consistently monitor and record temperatures and/or the presence of ice for these species. There were no monitoring records for the "display" critical control point. Similar violations were noted during the previous inspection at your facility on September 5 & 6, 2001 when a display of bluefish was noted without ice and an internal temperature of 50 degrees F, as well as

during an inspection on March 15 & 16, 2000 when a display of bluefish was noted with very little ice.

You have also failed to implement the record keeping system listed in your HAACP plan for the "storage" critical control point in that there were no records for your in-house refrigerated unit for the period 11/14/01 through 11/30/01.

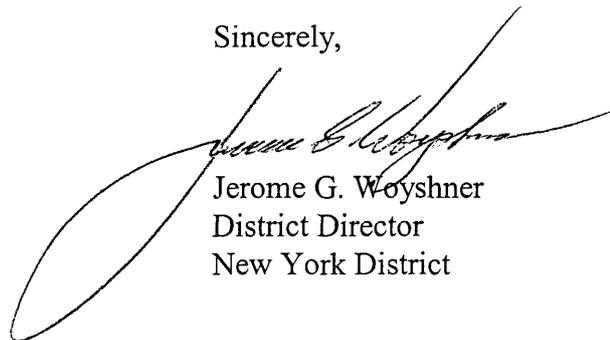
We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within 15 days 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 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 and the inspectional observations (Form FDA 483) issued to and discussed with you at the conclusion of the inspection, may not list all the deviations at your facility. You are responsible for ensuring that your seafood processing facility 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 Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Lillian C. Aveta, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Ms. Aveta at (718) 662-5576.

Sincerely,



Jerome G. Woyshner  
District Director  
New York District

Enclosure: Form FDA 483 issued on December 6, 2001