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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

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

August 20, 2002

**WARNING LETTER**

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

Ref: NYK-2002-44

Ms. Emily Siegal  
President  
Sunrise Seafood, Inc.  
111 South Street  
New York, NY 10038

Dear Ms. Siegal:

We inspected your firm, located at 111 South Street, New York, New York on June 28, 2002, July 3, 2002 and July 23, 2002, and found that you have a serious deviation 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). This deviation causes your raw histamine forming fish, such as mackerel, 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 deviation is 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 histamine producing species, such as king mackerel and bluefish, which is received, filleted, displayed and stored by your firm. Further, development, reassessment and modification of HACCP plans must be performed by an adequately trained or qualified individual as required by 21 CFR 123.10(a).

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

Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation. You may wish to include in your response documentation or other useful information that would assist us in

Sunrise Seafood, Inc. - NYK-2002-44

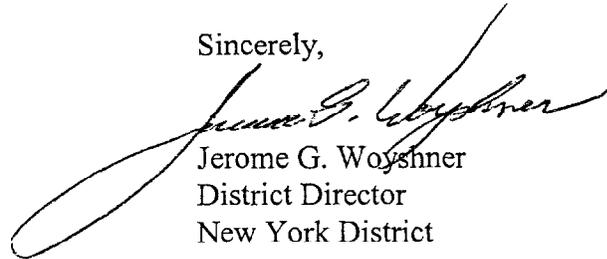
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evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

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 CGMP regulations. 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 dated July 3, 2002