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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

New York District

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

August 23, 2002

**WARNING LETTER**

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

Mr. David Smith  
President  
Arrow Seafood, Inc.  
22 Fulton Fish Market  
New York, NY 10038

Ref: NYK-2002-45

Dear Mr. Smith:

We inspected your firm, located at 22 Fulton Fish Market, New York, New York on July 19, 23, 26, 2002, 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 scombrototoxin (histamine) forming fish and refrigerated ready to eat fishery products 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 HACCP plans list monitoring frequencies which are not adequate to control the hazards:

a. At the street display critical control point, your HACCP plan for histamine forming fish lists monitoring the adequacy of ice every time a box is opened. During the inspection our investigator observed an opened box of escolar without adequate ice. The investigator measured the core temperature of the escolar to be 49°F. If the stored fish and fishery products are maintained on ice, the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition* recommends that ice be controlled with visual checks at least twice a day for histamine control.

b. At the storage critical control point your HACCP plan for refrigerated ready to eat fish lists monitoring the adequacy of ice daily to control pathogen growth. During the inspection our

investigator observed containers of perishable crab meat stored on the street without adequate ice. The investigator measured the temperature of the crab meat to be 47°F. If the stored fish and fishery products are maintained on ice, the *Fish & Fisheries Products Hazards & Controls Guidance: Third Edition* recommends that ice be controlled with visual checks at least twice a day for pathogen growth control.

2. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b):

a. Your firm did not record monitoring observations at the storage critical control point to control the histamine hazard listed in your HACCP plan for tuna and other histamine forming fish, such as, escolar. There are no records of the storage temperature or the adequacy of ice for fish stored in the storage cooler.

b. Your firm did not record monitoring observations at the street display critical control point to control the histamine hazard listed in your HACCP plan for non-tuna histamine forming fish, such as, escolar. There are no records of the temperature or the adequacy of ice for fish, other than tuna, stored in boxes on street display.

We may take further action if you do not promptly correct these deviations. For instance, we may take action without further notice to seize your products and/or enjoin your firm from operating.

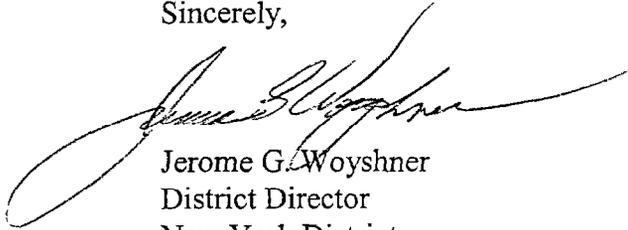
Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections.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

Arrow Seafood, Inc.  
Page# 3

Please send your reply to the Food and Drug Administration, Attention: Laurence D. Daurio, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issues in this letter, please contact Mr. Daurio at (718) 662-5585.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woyshner", with a large, sweeping flourish extending to the left.

Jerome G. Woyshner  
District Director  
New York District

Enclosure: Form FDA 483 dated July 26, 2002