



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

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New York District

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

October 3, 2001

**WARNING LETTER**

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

Ref: NYK-2002-1

Mr. James Hong  
President  
Hong's Merchandising Group  
16-20 Ash Street  
Brooklyn, NY 11222

Dear Mr. Hong:

We inspected your seafood processing facility, located at 16-20 Ash Street, Brooklyn, New York on August 14, 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 raw, ready-to-eat fish and vacuum packaged smoked and unsmoked salmon, squid, tuna, shrimp, eel, yellowtail snapper or 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 deviations included, but are not limited to, the following:

1. You must have written HACCP plans to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm did not have HACCP plans for:
  - raw, non-histamine, ready-to-eat fish to control the food safety hazards of parasites and pathogen growth, and
  - the receipt, display and storage of vacuum packed, ready-to-eat, smoked and unsmoked salmon, squid, tuna, shrimp, eel, yellowtail snapper or mackerel to control the hazard of *Clostridium botulinum*.

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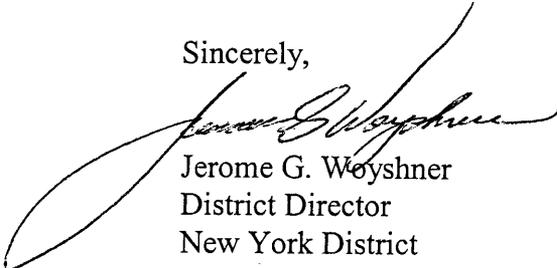
We may take further action if you do not promptly correct these deviations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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 Charles Hong, Vice President, 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 dated August 14, 2001