

93154d



DEPARTMENT OF HEALTH & HUMAN SERVICES

New York District

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Robert Leone
President
Haley's Comet Seafood Corp.
108 South Street
New York, NY 10038

August 9, 2002

Ref: NYK-2002-42

Dear Mr. Leone:

We inspected your firm, located at 108 South Street, New York, New York on June 27, 2002, July 3, 2002 and July 23, 2002, and found that you have serious deviations from the Seafood Hazard Analysis Critical Control Point regulations (Title 21, Code of Federal Regulations, Part 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption (21 CFR 110). These deviations cause your vacuum packaged ready-to-eat smoked, sliced salmon and raw histamine forming fish such as mahi mahi (dolphin fish) to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. §§ 301-97.

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. Prudent processors already take these kinds of measures. HACCP provides a systematic way of taking measures that demonstrates to us, your customers, and consumers that you routinely practice food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety-oriented workforce, less product waste, and fewer problems generally.

You can find the Act through the links in FDA's home page at www.fda.gov. The Center for Food Safety and Applied Nutrition web site link to HACCP information can be found at <http://vm.cfsan.fda.gov/seafood1.html>. The web site has a complete copy of the Fish & Fisheries Products Hazards & Controls Guide, Second Edition. You can use this guide to assist you in

developing your HACCP plan.

The deviations found during our inspection include, but are not limited to, the following:

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 vacuum packaged ready-to-eat smoked, sliced salmon to control the food safety hazard of clostridium botulinum toxin formation during receipt, display, and storage.
2. You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the receiving and storage critical control points to control the histamine hazard listed in your HACCP plan for histamine forming species.
3. You must maintain sanitation control records that document the sanitation conditions and practices during processing, to comply with 21 CFR 123.11(c). However, your firm did not have records of monitoring the eight areas of sanitation listed in 21 CFR 123.11(b).

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

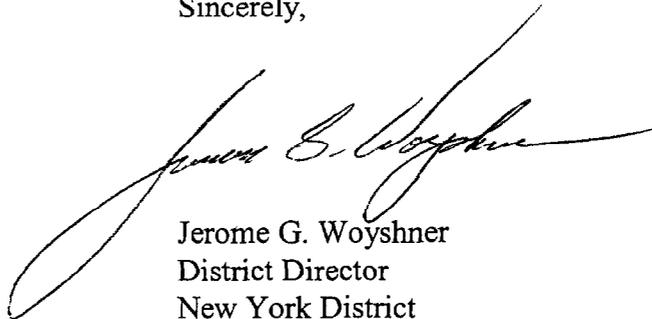
Please respond in writing within three weeks from your receipt of this letter. Your response should outline the specific things that you are doing to correct these deviations. You may wish to include in your response documentation or other useful information that would assist us in evaluating your corrections. 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 CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Haley's Comet Seafood Corp. - NYK-2002-42
Page# 3

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,

A handwritten signature in black ink, appearing to read "Jerome G. Woysner". The signature is fluid and cursive, with a large loop at the end.

Jerome G. Woysner
District Director
New York District

Enclosure: Form FDA 483 dated July 3, 2002