



DEPARTMENT OF HEALTH & HUMAN SERVICES

g18981
New York District

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Aaron Schwartz, President
Schwartz Appetizing, Inc.
4824 16th Avenue
Brooklyn, NY 11204

October 24, 2001

Ref: NYK-2002-6

Dear Mr. Schwartz:

We inspected your seafood processing facility, located at the above address, on September 13 and October 4, 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, some of which were previously brought to your attention, cause your ready-to-eat herring 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.

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

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations (i.e., refrigeration temperatures) at the storage critical control point to control the pathogen growth and *Clostridium botulinum* toxin formation hazards listed in your HACCP plan for ready-to-eat herring products.
2. 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 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 these deviations. You may wish to include in your response documentation or other useful information that would assist us

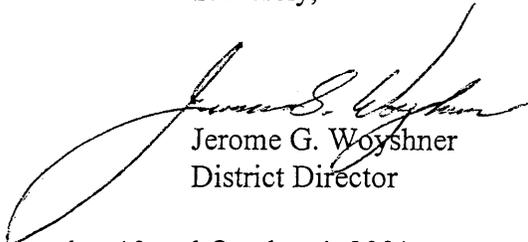
Schwartz Appetizing, Inc.
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in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter and the inspectional observations (Forms FDA 483) issued to and discussed with Isaac Schwartz, General Manager 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: Bruce A. Goldwitz, Compliance Officer, 158-15 Liberty Avenue, Jamaica, NY 11433. If you have questions regarding any issue in this letter, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,



Jerome G. Woyshner
District Director

Enclosures: Forms FDA 483 dated September 13 and October 4, 2001