



DEPARTMENT OF HEALTH & HUMAN SERVICES

34637d

New York District

Food & Drug Administration
158 - 15 Liberty Avenue
Jamaica, New York 11433-1034

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Herman Weinberger
Owner
Weinberger Appetizing
190 Division Avenue
Brooklyn, New York 11211

June 25, 2003

Ref: NYK-2003-28

Dear Mr. Weinberger:

We conducted an inspection at your firm, located at 190 Division Street, Brooklyn, New York 11211 on May 21st & 22nd, 2003, and found your firm has serious deviations from Title 21 of the Code of Federal Regulations (CFR), Part 123 - Fish and Fishery Products (seafood Hazard Analysis Critical Control Point ("HACCP") regulations). An FDA 483 Inspectional Observations form (copy enclosed) listing the deviations was issued to you at the conclusion of the inspection. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act). Accordingly, your packaged ready-to-eat, pickled herring products are adulterated, in that the products have been prepared, packed, or held under unsanitary conditions whereby they may have been rendered injurious to health.

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.

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

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR, Part 123.6(a) and (b). However, your firm does not have a HACCP plan for refrigerated, ready-to-eat, pickled herring to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse;
2. You must adequately monitor and maintain records of monitoring sanitation conditions and practices during processing, to comply with 21 CFR, Part 123.11(b) and (c). However, your firm did not monitor and has no sanitation monitoring records required for the processing of refrigerated ready-to-eat fishery products; and
3. Failure to have an individual who has successfully completed appropriate HACCP training, or who is otherwise qualified through job experience to develop a HACCP plan and reassess and modify the HACCP plan in accordance with the corrective action procedures or verification activities (21 CFR, Part 123.10).

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 Current Good Manufacturing Practice (CGMP) regulations (Title 21 CFR, Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

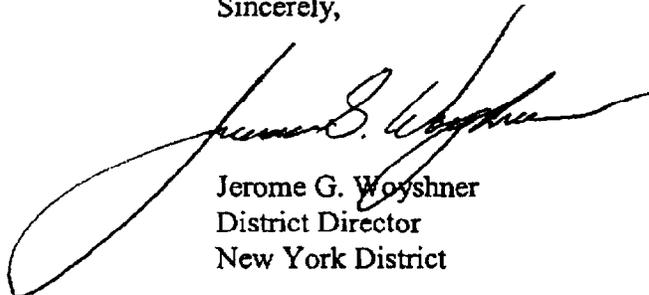
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within 15 working days 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 such as your revised HACCP plan, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect you will explain the reason for your delay and state when you will correct any remaining deviations.

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Please send your written reply to the Food & Drug Administration (FDA), Attention: Arthur S. Williams, Jr., Compliance Officer, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have questions regarding any issues in this letter, please contact Mr. Williams at (718)662-5568.

Sincerely,

A handwritten signature in black ink, appearing to read "Jerome G. Woysner", written in a cursive style with a large loop at the end.

Jerome G. Woysner
District Director
New York District

Enclosure:

Form FDA 483, Dated May 22nd, 2003
