



DEPARTMENT OF HEALTH & HUMAN SERVICES

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New York District

JUN 17 2004

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

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Hamidur Rahman, Vice President
Euro Foods USA, Inc.
1075 Flushing Avenue
Brooklyn, NY 11237-1808

Ref: NYK-2004-19

Dear Mr. Rahman:

On April 21, 2004, the Food and Drug Administration (FDA) conducted an inspection of your facility at the above address.

This inspection focused on one of the seafood products imported by your firm, frozen Hilsa fish. The inspection revealed that your firm continues to have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulations, found at Title 21, Code of Federal Regulations, Part 123 (21 CFR Part 123). Seafood that is processed in violation of the HACCP regulations is adulterated, within the meaning of Section 402 (a) (4) of the Federal Food, Drug, and Cosmetic Act (the Act), because it had been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find this Act and the seafood HACCP regulations through links on FDA's home page at (www.fda.gov).

During our inspection, the FDA investigator provided Mr. Hamidur Rahman, Vice President, with a copy of the Import Seafood HACCP Report (Form FDA 3502), which presents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP requirements. The investigator also provided him with a copy of the List of Inspectional Observations (Form FDA 483 - copy enclosed). The inspectional observations of concern to us are as follows:

1. You must have and implement product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for frozen Hilsa fish imported from [REDACTED].

2. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for frozen Hilsa fish, imported from [REDACTED] in [REDACTED].

Additionally, previous inspections of your facility conducted by FDA revealed that other seafood products are imported by your firm for which similar failures to comply with the seafood HACCP requirements were observed.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products imported and distributed by your firm are in compliance with the Act and all requirements of its implementing regulations.

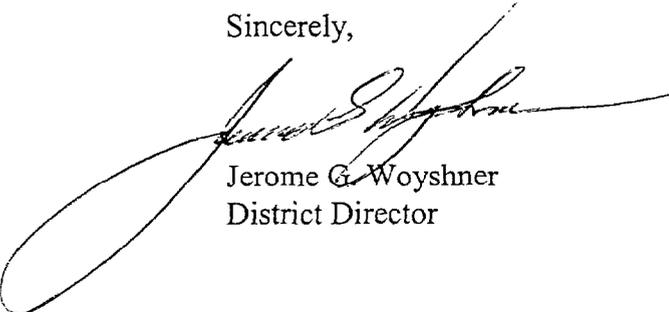
You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Health Certificates for any of the effected fish and fishery products processed at your facility.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your reply relating to these concerns should be directed to the Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, NY 11433, Attention: Herman B. Janiger. If you have questions regarding the implementation of the HACCP regulations, you may contact Mr. Janiger at (718) 662-5477 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program at your facility.

Sincerely,



Jerome G. Woysner
District Director