



January 15, 2003

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-7-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Jimmy B. Wong, Owner
Lien Hoa Food Corporation
1111 W. Pershing Road
Chicago, IL 60609

Dear Mr. Wong:

On November 1, 2002, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 1111 W. Pershing Rd., Chicago, Illinois. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations under Title 21, Code of Federal Regulations, Part 123, (21 CFR 123).

Your firm is an importer and distributor of specialty Asian foods including seafood. Your firm is also a food warehouse. The FDA investigator provided you with a copy FDA's performance evaluation of your firm regarding various aspects of the seafood HACCP requirements. The observations of concern to us are as follows:

- There were no written specifications available for any of the imported seafood products including frozen steamed mackerel from [REDACTED]. You must have 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).
- Your firm has not implemented any affirmative step for its imported seafood products including frozen steamed mackerel from [REDACTED]. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii).

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 processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

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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 Union Health Certificates for any of the affected 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 reoccurrence. 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, Attention Paul Boehmer, Compliance Officer at the above District FDA office.

If you have questions regarding the implementation of the HACCP Regulations, you may contact Darrell Luedtke, the District Seafood HACCP coordinator, telephone (847) 249-8632, 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.

Sincerely,

\s\

Arlyn H. Baumgarten
District Director