



June 1, 1999

WARNING LETTER  
CHI-21-99

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

David S. Wong, President  
Pioneer Live Shrimp, Inc.  
163 N. Aberdeen  
Chicago, IL 60607

Dear Mr. Wong:

On March 11 and 15, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to the State of Illinois inspection in July 1998. The State's inspection covered the new FDA Hazard Analysis Critical Control Point (HACCP) regulations. This FDA inspection was made again, to evaluate HACCP requirements. At the conclusion of the inspection, you were presented with form FDA-483, List of Observations, and Form FD-3501, Domestic Seafood HACCP Report. The reports describe deviations to FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for Human Food (21 CFR 110). By virtue of these violations, the seafood products processed at this facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigators found the following continued violations:

- Failure to prepare and implement a HACCP plan/s to control a food safety hazard/s that is reasonably likely to occur. Examples include: hazards of drugs and/or chemicals in aqua cultured fresh unprocessed fish such as carp and catfish.

You should take prompt action to correct these violations. Although improvements were reported, we are concerned that no substantial corrections were made since the inspection in July 1998. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. We are also providing firms the opportunity to take a HACCP refresher course to assist in better understanding and working with the Seafood HACCP program. Please contact the local FDA office for further information. If you enroll in one of these courses, we will extend your response time or further regulatory action provided products are not critically compromised resulting in a danger to health.

We also observed the following continued deviations to your domestic seafood HACCP operations:

- Failure to monitor and record sanitation conditions and corrective actions (Reference - 21 CFR Section 123.11 and Part 110). These deviations were in areas of concern as follows:

Condition and cleanliness of food contact surfaces;  
Prevention of cross contamination;  
Maintenance of hand washing and hand sanitizing facilities;  
Protection from adulteration;  
Proper labeling, storage and use of toxic compounds;  
Control of employee health conditions; and  
Exclusion of pests.

In addition, we determined that some of your operations are defined under the import requirements of the regulations, so we also evaluated your import program under the seafood HACCP regulations. These requirements became effective on the same date as the requirements for domestic operations and can be found in 21 CFR 123.12. At the conclusion of the inspection, the investigators also issued an Importer Seafood HACCP Report Form 3502. Deficiencies concerning documents for the one species of fish ( [REDACTED] ) covered under the Import Program are included as follows:

- Lack of adequate importer verification, i.e., there is no written documentation of affirmative steps on file to verify the acceptability of the supplier of the [REDACTED].
- Specifications for the [REDACTED] from [REDACTED] lack adequate safety limits.

The violations cited are not all inclusive since not every product could be evaluated at the time. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. Your reply relating to these concerns should be directed to the attention of Paul Boehmer, Compliance Officer.

Sincerely,

/s/  
Raymond V. Mlecko  
District Director