



DEPARTMENT OF HEALTH & HUMAN SERVICES

1130391  
HFE-35

Public Health Service  
Food and Drug Administration  
6751 Steger Drive  
CINCINNATI DISTRICT OFFICE  
Cincinnati, OH 45237-3097

April 12, 2000

**WARNING LETTER**  
**CIN-WL-00-1549**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Larry Keckles  
Tri-County Food Service  
11371 Williamson Road  
Blue Ash, OH 45241

Dear Mr. Keckles:

On January 11 and 13, 2000 the Food and Drug Administration (FDA) conducted an inspection of your plant located in Blue Ash, Ohio. The inspection was conducted to determine the compliance with the Seafood Processing Regulations (21 CFR 123) and the Good Manufacturing practices requirements for foods (21 CFR 110).

During the inspection, the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator provided you with a copy of the Domestic Seafood HACCP Report (FDA 3501) and the FDA 483 which represents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. Your firm is in violation of 21 CFR 110 and 123 covering your products to be deemed adulterated under provision of 21 U.S.C. 342(a)(4) because of the following:

- A) Failure to have and implement a written HACCP plan for each type fish product manufactured.
- B) Failure to establish sanitation standard operation procedures to monitor and control safety of water, condition and cleanliness of food contact surfaces; cross contamination; maintenance of hand washing and sanitation facilities; toilet facilities; protection of food from cleaning compounds and lubricants; proper labeling of toxic compounds; microbial contamination from employee health conditions and the exclusion of pests. There are no records of these items being controlled and/or monitored.

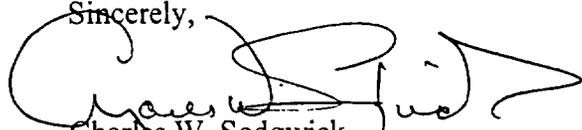
It is essential that you respond to this office on this matter within 15 working days of receipt of this letter. If corrections are not made FDA may initiate regulatory action such as civil seizure injunction without further notice.

At the conclusion of the inspection the inspector told you the agency requested a response within 30 days in regards to items found during his inspection. Had you done so, you could have been specifically invited to attend HACCP Certification Training at Cincinnati District Office 3/6-8/2000.

Your reply relating to these concerns should be directed to the Food and Drug Administration, attention Leonard Jay Farr, Compliance Officer. If you have any questions concerning implementation of the HACCP regulations (21 CFR 123) to your specific processes, you may contact Mr. Farr at 513-679-2700 for answers and/or direction towards guidance and sources of training in achieving compliance.

Please note our previous correspondence to you on April 1, 1999 (re UL 1999-203) inaccurately referenced a facility in Louisville, Kentucky and the date 9/1-2/99. We should have referenced your Blue Ash facility and the date March 1-2, 1999.

Sincerely,



Charles W. Sedgwick  
Acting District Director

CWS/jp