



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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4/18/00*

Public Health Service

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Food and Drug Administration
New Orleans District Office
Nashville Branch
297 Plus Park Blvd.
Nashville, TN 37217

April 18, 2000

Certified Mail—Return Receipt Requested

Kham Seafood
11125 Beverly Road
Irvington, AL 36544

ATTN: Kham Khemmanivanh
Owner

Warning Letter No. 00-NSV-14

Dear Mrs. Khemmanivanh:

We inspected your firm, located at 11125 Beverly Road, Irvington, Alabama, on September 8-14 and 17, 1999, and found serious deviations from the seafood HACCP regulations (21 CFR 123) and the current good manufacturing practice requirements for foods (21 CFR 110). These deviations, some of which were previously brought to your attention, cause your crab meat to be adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and aforementioned regulations on the Internet through links in the Food and Drug Administration (FDA) home page at www.fda.gov. (If you do not have access to the Internet, we will furnish you copies on request.)

The noted deviations were as follows:

- You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not take internal crab temperatures every two hours at the backing and cooling critical control points or the picking and packing critical control point as specified in your HACCP plan. Our investigator found a temperature of 57°F in the crab meat on the picking table and the critical limit in your plan is 50°F. Further, your Daily Cooked Crab Cooler Log records routinely omitted entries for the 2 hour and/or 6 hour checks to show that critical temperature limits were not being exceeded. We are concerned that these practices increase the likelihood of pathogen growth and toxin formation in your cooked crab meat.
- You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the picking and packing critical control point to control pathogen growth and toxin formation.
- You must adequately monitor sanitation records and practices during processing to comply with 21 CFR 123.11(b).

Other conditions and practices of serious concern are detailed on the list of inspectional observations issued to and discussed with Mr. Ray P. Khemmanivanh, Manager, at the termination of the inspection.

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

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing or have done to correct any deviations. You may wish to include in your response documentation such as copies of any revised records or changes made to your HACCP plan. If you cannot complete all corrections before you respond, we expect you to explain the reason(s) for any delay and furnish us an estimate of when you expect to correct any remaining deviations.

This letter does not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act and any relevant regulations.

Please send your reply to the attention of Frank J. Jancarek, Compliance Officer, at the above letterhead address. If you have questions regarding any issue in this letter, please contact Mr. Jancarek at 615-781-5390, extension 126.

Sincerely,



Richard D. Debo
Acting Director, New Orleans District

RDD:FJJ:man