



JAN 3 2001

Mr. Zenghou Pang  
Factory Director  
Qingdao Kangda No. 2 Cold Storage Plant  
83 East Tieshan Road  
Jiaonan, Qindao  
P.R. China

### WARNING LETTER

Dear Mr. Zenghou Pang:

We inspected your firm located at 83 East Tieshan Road, Jiaonan, Qindao on May 22-23, 2000 and found that you have serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123). These deviations cause your frozen boiled short-neck clam meat to be in violation of section 402(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

1. You must have a HACCP plan that lists the appropriate critical control points, to comply with 21 CFR §123.6(c)(2). Your firm's HACCP plan for frozen boiled short-neck clam meat does not list the critical control point of post-processing contamination for controlling the food safety hazards of pathogen growth and toxin formation. Chapter 12 of the Fish and Fishery Products Hazards & Controls Guide: Second Edition addresses the hazards related to pathogen growth and provides examples of how to control the hazard.
2. You must have a HACCP plan that lists adequate monitoring procedures for each critical control point, to comply with 21 CFR §123.6(c)(4). However, your firm's HACCP plan for frozen boiled short neck clam meat lists a monitor procedure at the steam boiling critical control point that is not adequate to control pathogen survival through cooking. The monitoring procedures listed in your HACCP plan do not ensure adequate monitoring of exact start and stop times. Review of your records revealed that total cook time in minutes (i.e., 7 minutes), rather than the actual times for the starting and stopping of the cook cycle are recorded. You must monitor and record the actual start and stop times of the steam boiling (cook) critical control point.

3. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR §123.6(c)(7). However, your firm did not record the monitoring observation of steam pressure at the steam boiling critical control point. Discussions revealed that the steam pressure operator checks the pressure gauge, but does not record the reading.
4. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR §123.11(b). However, your firm did not monitor the safety and adequacy of the sanitary quality of the water that comes into contact with food with sufficient frequency to ensure its quality. This was evidenced by the fact that your firm does not chlorinate or otherwise treat the processing water to ensure sanitary quality. In addition, no residual chlorine was detected in the water that was sampled.

Please respond in writing within six (6) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response, documentation of your amended HACCP plan, copies of completed monitoring records and/or other useful information that would assist us in evaluating your corrections and their implementation. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on “Detention Without Physical Examination”.

This letter may not list all the deviations at the facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug and Cosmetic Act and all applicable regulations.

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Please send your reply to the Food and Drug Administration, Attention: Brian S. Landesberg, Consumer Safety Officer, Office of Field Programs, Division of Enforcement and Programs Import Branch, HFS-606, 200 C Street S.W., Washington, DC 20204. If you have questions regarding any issue in this letter, please contact Mr. Landesberg at (202) 205-5247.

Sincerely,

A handwritten signature in black ink, appearing to read "Ju Gushee". The signature is fluid and cursive, with the first name "Ju" and last name "Gushee" clearly distinguishable.

Judith A. Gushee

Director

Division of Enforcement and Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition