



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Food and Drug Administration
New Orleans District
Southeast Region
8600 Plaza Drive, Suite 400
New Orleans, LA 70127

Telephone: 504-253-4519
FAX: 504-253-4520

March 26, 2003

WARNING LETTER NO. 2003-NOL-14

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Phonekeo P. Viravong, President
Gulf Coast Crab International Co., Ltd
10380 Footh Road
Grand Bay, Alabama 36541

Dear Mrs. Viravong:

On February 5 – 11, 2003, we inspected your importer/storage facility for pasteurized crabmeat, located at 10380 Footh Road, Grand Bay, Alabama. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). The deviations cause your imported pasteurized crabmeat to violate Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at <http://www.fda.gov>.

The observations of concern to us are as follows:

- You must take affirmative steps to ensure that the fishery product you import, namely pasteurized crabmeat in plastic containers, manufactured by [REDACTED] in Thailand, is processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm does not have adequate written verification procedures and did not take affirmative steps to ensure that the pasteurized crabmeat was processed in accordance with seafood HACCP regulations. This is evidenced by the following:
 - You substituted the process and HACCP plan developed for pasteurized crabmeat in metal cans as the basis for pasteurized crabmeat in plastic containers; and,
 - You presented inadequate documentation (studies, etc.) to support the pasteurization process. The study does not identify the number of product containers in each batch tested, the container specifications, or the product formulation.

Under 21 CFR 123.12(a)(2)(ii)(D), if you take affirmative steps by maintaining the foreign HACCP plan on file, you also must maintain on file a written guarantee from each foreign

processor stating they are operating in compliance with 21 CFR 123. You have no written guarantee from [REDACTED], Thailand.

- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as “the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.” However, the processor’s HACCP plan for pasteurized crabmeat in metal containers does not list a critical limit of the length of the pasteurization cycle and the minimum water bath temperature at the pasteurization critical control point to control the hazard of pathogen growth and survival. Also, the processor’s HACCP plan lists a critical limit of [REDACTED], whereas your pasteurization study for this product states that [REDACTED] should be reached.
- You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm does not maintain sanitation control records for the following: safety of water that comes into contact with food or food contact surfaces; safety of water used to manufacture ice; condition and cleanliness of food contact surfaces; prevention of cross-contamination; maintenance of hand-washing, hand-sanitizing, and toilet facilities; protection of food, food packaging material, and food contact surfaces from adulteration with contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in microbiological contamination; and, exclusion of pests from the facility.

This letter may not list all the deviations at your 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 110. You also are responsible for using procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, the FDA may detain your imported seafood products without examination.

We are aware that you made a verbal commitment to correct the deviations during the inspection. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things that you are doing to correct these deviations. You should include in your response documentation such as copies of your revised HACCP plan and written verification procedures or other useful information that would assist us in evaluating your corrections. 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.

Please send your reply to the U.S. Food and Drug Administration, Attention: Cynthia R. Crocker, Compliance Officer, at 100 West Capitol Street, Jackson, MS 39269. If you have questions regarding any issue in this letter, please contact Ms. Crocker at (601) 965-4581.

Sincerely,

A handwritten signature in black ink that reads "F. Dwight Herd". The signature is written in a cursive style with a large, prominent "F" and "H".

F. Dwight Herd
Acting District Director
New Orleans District

Enclosure: Form FDA 483