



NOV 15 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Sompong Makcayathorn
Marketing Director
I.C.C. Cosmos Company, Ltd.
Moo 3, Tambol Bangtorad
Amphur Muang, Samutsakorn
Thailand

Dear Mr. Makcayathorn:

We inspected your firm located at Moo 3, Tambol Bangtorad, Amphur Muang, Samutsakorn, Thailand, on May 21, 2000, and found that you have serious deviations from the U.S. Seafood HACCP regulation (21 CFR, Part 123). These deviations, some of which were previously brought to your attention, cause your **frozen raw and cooked shrimp** 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 Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must take an appropriate corrective action when a deviation from your critical limits occur to comply with 21 CFR 123.7 (a). However, your firm failed to take corrective action to control the hazard of aquaculture drugs in both **Frozen Raw and Frozen Cooked Shrimp**. The firm tested a lot of Frozen Raw Shrimp on January 30, 2000, and the samples tested positive for oxytetracycline. The corrective action directed by the firm's HACCP plan called for rejection of the product back to the supplier. Your firm took no corrective action and shipped the hazardous product.

You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b)(8). However, your firm did not monitor the exclusion of pests (21 CFR 123.11(b)(8), with sufficient frequency to assure that pests were excluded from your processing plant, as evidenced by the inspection report noting the presence of insects in several areas of the processing facility where ready-to-eat product (cooked shrimp) was being produced.

You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(c)(1). However, your firm's HACCP plan for both **Frozen Raw Shrimp and Frozen Cooked Shrimp** does not list the food safety hazard of sulfites. Records indicate that incoming raw materials are routinely tested for the presence of sulfites with consistently positive results, proving that our firm had direct knowledge of the hazard but took no action to provide controls.

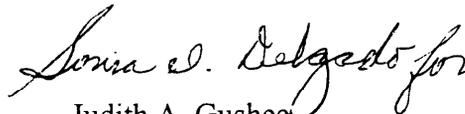
If the products bear a chemical preservative (e.g., sulfites) and their labels fail to declare the presence of the chemical preservative along with a separate description of the preservative's function in the ingredient statement, then the products are also misbranded under Section 403 of the Act. They are fabricated from two or more ingredients, but their labels fail to bear the common or usual name of the chemical preservative along with a separate description of the preservative's function [403(i)(2) and 403 (k)].

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 such as copies of your new and/or revised HACCP plan(s), one week of Raw Material Receiving monitoring records, or other useful information that would assist us in evaluating your corrections. If you believe the hazards listed above are not reasonably likely to occur in your products, you must provide the FDA with adequate written documentation that clearly supports your reasoning. 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 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, Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Frank Sikorsky, Consumer Safety Officer, Office of Field Programs, Division of Enforcement and Programs, Import Branch, HFS-606, 200 C Street SW, Washington, D.C. 20204. If you have questions regarding any issue in this letter, please contact Mr. Sikorsky at (202) 205-1955.

Sincerely yours,



Judith A. Gushee

Director

Division of Enforcement and Programs

Office of Field Programs

Center for Food Safety

and Applied Nutrition