



April 9, 2001

WARNING LETTER  
CHI-26-01

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ms. Hien T. Lam, President  
Van Lang Food Products, Inc.  
88 N. Eisenhower Lane  
Lombard, IL 60148

Dear Ms. Lam:

On August 21, 22 and 24, 2000, an investigator with the Food and Drug Administration (FDA), conducted an inspection of your plant. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for foods (21 CFR 110). We regret our delay in responding to you in this matter.

The inspection found that you have serious deviations from the Seafood HACCP regulations. These deviations, some of which were previously brought to your attention, cause your cooked seafood products processed with and without a batter mix, and raw salted seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the 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).

These serious deviations are as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for seafood products that are processed with a batter mix to control the food safety hazard of *Staphylococcus aureus* (*S. aureus*) toxin formation. Your batter operation does not include time and temperature monitoring of the batter mix.
- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for:
  - Cooked seafood (without a batter mix) does not identify the pre-cook processing step and the cooling step as critical control points for *S. aureus* and *Bacillus cereus* (*B. cereus*) growth and toxin formation. Your firm's procedures for this operation do not include monitoring internal temperature of seafood product at these steps, and do not include a record for the monitoring you perform of operational time elapsed at these steps.

- Uncooked seafood, which includes seafood product that contains salt, does not identify the processing step as a critical control point for *S. aureus* and *B. cereus* growth and toxin formation. Your operation does not include monitoring of internal temperature of seafood product at this step.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not follow the monitoring/documentation procedures as follows:
  - Protection of product from adulterants, i.e. a production worker without gloves was wearing a ring and another was wearing a bracelet while handling vegetable spring rolls; a third worker without gloves rubbed her nose with her hands and continued to fill spring rolls without washing/sanitizing hands.

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

Please respond in writing within 15 working days 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 updated HACCP plans, critical control points, critical limits, time/temperature monitoring records, sanitation monitoring records with corrective action reports 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.

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 (21 CFR Part 123) 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: Paul Boehmer, Compliance Officer at the Chicago District Office, 300 S. Riverside Plaza, Suite 550 South, Chicago, IL 60606. If you have questions regarding the implementation of the HACCP regulations or the application of HACCP to your specific process, you may contact Investigator Darrell Luedtke at the Gurnee Office for answers and/or direction about guidance and sources of training in achieving compliance. His telephone number is (847) 249-8632, extension 28.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director