



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

91035d

60 8th Street, N.E.  
Atlanta, Georgia 30309

March 20, 2001

**VIA FEDERAL EXPRESS**

Sengiri Angkawijana, President/Owner  
Imaex Trading Company, Inc.  
5405 Buford Highway, Suite 350  
Norcross, GA 30071

**Warning Letter**

01-ATL-31

Dear Mr. Angkawijana:

On October 18-19, 2000, the Food and Drug Administration (FDA) conducted an inspection of your importing operation located at Norcross, Georgia. Our investigator documented deviations from FDA's seafood HACCP importing regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause the frozen raw shrimp imported by your firm 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 the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviation of concern is as follows:

You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for the Frozen Raw Aquacultured Shrimp imported from Indonesia.

You should take prompt measures to correct this deviation. Failure to promptly correct this deviation may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination until your firm is fully in compliance with the Seafood HACCP regulation.

Please respond in writing, within three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct this deviation, including an explanation of each step taken to prevent the recurrence of similar deviations. 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.

Your written reply should be directed to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have any questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277

Sincerely,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director *for*  
Atlanta District