



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

g 3166d

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

August 15, 2002

Our Reference: 2954542

Kuncheung Lin, President
Linma International (USA), Inc.
1308 Bayshore Highway, Suite 228
Burlingame, California 94010

WARNING LETTER

Dear Mr. Lin:

We inspected your seafood firm on November 14 and 16, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123.

We found that your firm had serious HACCP deviations. These deviations caused your Aquacultured Shrimp to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the fish had been prepared, packed, or held under insanitary conditions, whereby they may have been rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with Mr. Kun-Fa Lin, Vice President, at the conclusion of the inspection. We are enclosing a copy of the Form FDA 483 for your reference. Your serious HACCP deviations are as follows:

1. You must have product specifications that are designed to ensure that fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm had a product specification for Aquacultured Shrimp, imported from [REDACTED], that did not address the food safety hazard of aquaculture drugs that is reasonably likely to be present in aquaculturally grown shrimp.
2. You must implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm's

performance of affirmative step Option D under 21 CFR 123.12(a)(2)(ii) of maintaining on file a copy, in English, of the foreign processor's HACCP plan for Frozen Peeled (tail-on or tail-off), Deveined, or Undeveined Shrimp, manufactured by [REDACTED] was inadequate. Specifically, the foreign processor's HACCP plan did not list the food safety hazard of aquaculture drugs.

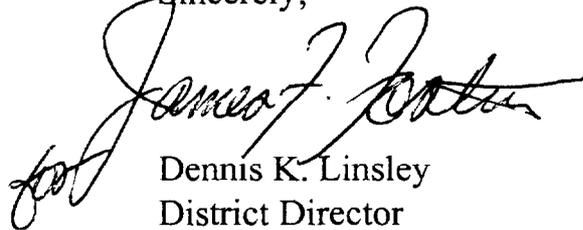
Over nine months have elapsed since the FDA inspection. You have had sufficient time to correct the violations. We may initiate regulatory action without further notice if you have not corrected these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may detain your imported seafood products without examination.

The above-identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,



Dennis K. Linsley
District Director
San Francisco District

Enclosure: Form FDA 483
cc: Kun-Fa Lin, Vice President