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

VIA FEDERAL EXPRESS

October 10, 2001

Our Reference: 2954048

Kuo S. Wang, President
Lian Hwa Foods (U.S.A.), Inc.
239 South Maple Avenue
South San Francisco, California 94080

WARNING LETTER

Dear Mr. Wang:

We inspected your seafood firm on September 12, 13, and 24, 2001. We conducted this inspection to determine your compliance with FDA's seafood processing regulations, 21 Code of Federal Regulations (21 CFR 123) and the Good Manufacturing Practice (GMP) requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your Dried Shredded Squid and Dried Fish With Almonds 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 have been prepared, packed, or held under insanitary conditions, whereby they may be rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. Your serious HACCP violations 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 does not have product specifications for the following:

- (a) Dried shredded squid (from [REDACTED]), to ensure control of the food safety hazards of potential pathogen growth and toxin formation from inadequate drying of the product.
- (b) Dried Fish With Almonds (from [REDACTED]), to ensure control of the food safety hazards of *Clostridium botulinum*, histamine, and pathogen growth and toxin formation from inadequate drying of the product.

The above-identified deviations are not intended to be an inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by

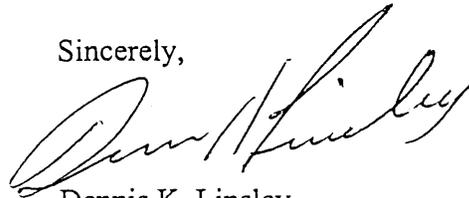
your firm are in compliance with the Federal Food, Drug, and Cosmetic Act and all requirements of the federal regulations.

You must immediately take appropriate steps to correct these deviations. We may initiate regulatory action without further notice if you do not correct the deviations. Regulatory action may include seizure and/or injunction. In addition, we may detain your imported seafood products without physical examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct these violations. 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 violations.

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,

A handwritten signature in cursive script, appearing to read "Dennis K. Linsley".

Dennis K. Linsley
District Director
San Francisco District