



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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

VIA FEDERAL EXPRESS

1-12-2000

Our Reference: 2954062

David C. Lan, President
L & W Group, Inc.
30845 Huntwood Avenue
Hayward, California 94544

WARNING LETTER

Dear Mr. Lan:

We inspected your seafood firm on July 7, 1999. 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 requirements for foods (21 CFR 110).

We found that your firm has serious HACCP deficiencies. The deficiencies cause your frozen cuttlefish balls, fish balls, shrimp balls, canned eel, canned tuna, and frozen broiled catfish 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 has been prepared, packed or held under insanitary conditions, whereby they may be rendered injurious to health. We discussed these deficiencies with Mrs. Juno Lan, Secretary and Treasurer, at the conclusion of the inspection and attached is a copy of the Form FDA 483 for your reference. Your serious HACCP violations are as follows:

1. You must have written product specifications that are designed to ensure that the the products that you import are not adulterated under Section 402 of the Federal Food, Drug, and Cosmetic Act, in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for:

- fish balls from Taiwan to address the food safety hazards of *pathogen survival through cooking* and *histamine formation* (in fish balls containing mackerel);

- shrimp balls from Taiwan to address the food safety hazards of *pathogen survival through cooking* and *sulfites*; and,
- cuttlefish balls from Taiwan to address the food safety hazard of *pathogen survival through cooking*.

2. You must have written product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under Section 402 of the Federal Food, Drug, and Cosmetic Act, in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for:

- canned tuna from Taiwan to ensure control of the food safety hazard of *histamine formation*;
- canned eel from Taiwan to ensure control of the food safety hazards of *chemicals, aquaculture drugs, and Ciguatera toxin*; and,
- frozen broiled catfish from Taiwan to ensure control of the food safety hazards of *chemicals, aquaculture drugs, and pathogen survival through cooking*.

3. You must take affirmative steps which ensure that the fish and fishery products you import were processed in accordance with the requirements of 21 CFR Part 123, in order to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform affirmative steps for:

- canned tuna from Taiwan to ensure control of the food safety hazard of *histamine formation*;
- canned eel from Taiwan to ensure control of the food safety hazards of *chemicals, aquaculture drugs, and Ciguatera toxin*; and,
- frozen broiled catfish from Taiwan to ensure control of the food safety hazards of *chemicals, aquaculture drugs, and pathogen survival through cooking*.

You must immediately take appropriate steps to correct the violations at your facility. We may initiate regulatory action without further notice if you do not correct these problems. Regulatory action may include seizure, injunction, or detention of future shipments without physical examination.

We acknowledge Mrs. Lan's response of September 28, 1999, to the inspectional observations presented to her at the close of the inspection. She has addressed item 1 from the list of violations but did not provide corrective steps for the other two items.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have implemented to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795, FAX: 510-337-6707).

Sincerely,

A handwritten signature in cursive script that reads "Charles D. Moss".

Charlie D. Moss
Acting Director
San Francisco District

Enclosure