



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

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

VIA FEDERAL EXPRESS

October 5, 2000

Our Reference: 2954173

Hyo K. Lim, President
H & K Inc., dba Palama Supermarket
1210 Dillingham Boulevard
Honolulu, Hawaii 96817

WARNING LETTER

Dear Mr. Lim:

We inspected your seafood firm on May 5, 2000. 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). The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements.

We found that your firm has serious HACCP deficiencies. These deficiencies cause your seafood products, specifically dried anchovies and canned boiled mackerel, 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 written product specifications that are designed to ensure that the fish and fishery products that you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, during our inspection on May 5, 2000, we found, for example, that you did not have product specifications for the following two products:

- (a) Dried anchovies from [REDACTED], to address potential pathogen growth and toxin formation, including *Clostridium botulinum* and *Staphylococcus aureus*, as a result of inadequate drying, and the potential hazard of histamine formation as a result of time/temperature abuse.
- (b) Canned mackerel from [REDACTED], to ensure control of the potential hazard of histamine formation as a result of time/temperature abuse of the fish.

2. You must implement an affirmative step that ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for dried anchovies and canned mackerel to verify that the products were processed in accordance with the seafood HACCP regulations.

This letter may not list all of the deviations at your facility. You are responsible for ensuring that all of your products are in compliance with applicable statutes enforced by the FDA. You also have the responsibility to use procedures to prevent further violations of the FD&C Act, the seafood HACCP regulations, and other applicable regulations enforced by the FDA.

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 and/or injunction. Furthermore, your firm and the foreign processor may be placed on import alert, and future shipments of the products may be subject to detention without physical examination.

Please respond in writing within fifteen (15) working days from receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You may wish to include in your response, documentation such as copies of product specifications, verification plans, your foreign processors' HACCP plans, or other useful information that would assist us in evaluating your corrections. 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,



Darrell T. Lee
Acting Director
San Francisco District