



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

November 14, 2001

Our Reference: 2953824

Trung Dang, President
Sun Hing Foods, Inc.
271 Harbor Way
South San Francisco, California 94080

WARNING LETTER

Dear Mr. Dang:

We inspected your seafood firm on October 15 and 17, 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 and GMP deviations. These deviations cause your Ready-to-eat Shrimp and Crab Meat 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 deviations on a Form FDA 483 and discussed them with Ms. Virginia Teng, Vice President, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP deviations are as follows:

1. 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 product specifications for the following:

- (a) Bottled Shrimp (from [REDACTED]), to ensure control of the food safety hazards of allergens such as sulfiting agents, and glass inclusion that is reasonably likely to be presented by the product.
- (b) Canned Crab Meat (from [REDACTED]) to ensure control of the food safety hazard of allergens such as sulfiting agents that is reasonably likely to be presented by the product.

2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for the following areas of sanitation:

- (a) Protection of food, food packaging material, and food contact surfaces from adulterants;
- (b) Proper labeling, storage, and use of toxic compounds; and
- (c) Exclusion of pests from the facility.

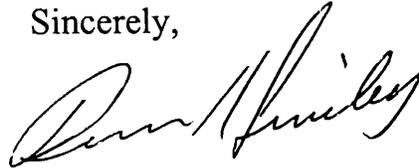
You must immediately take appropriate steps to correct the deviations at your facility. We may initiate regulatory action without further notice if you do not correct them. For instance, we may take further action to seize your products and/or enjoin your firm from operating. In addition, we may detain your imported seafood products without examination.

The above-identified deviations are not intended to be an inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products distributed by your firm are in compliance with the Federal Food, Drug, and Cosmetic 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 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 black ink, appearing to read "Dennis K. Linsley". The signature is fluid and cursive, with the first name "Dennis" being more prominent and the last name "Linsley" following in a similar style.

Dennis K. Linsley
District Director
San Francisco District

Enclosure: FDA 483

cc: Ms. Virginia Teng, Vice President