



WARNING LETTER

19701 Fairchild
Irvine, California 92612-2506
Telephone (949) 608-2900

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

August 29, 2003

Mr. Chan, President
Hung Chong Lung Inc.
16578 Valley Blvd.
La Puente, CA 91744

W/L 49-03

Dear Mr. Chan:

On June 11 - 18, 2003, the Food & Drug Administration (FDA) conducted an inspection of your facility located at 16578 Valley Blvd., La Puente, CA 91744. The inspection was conducted to determine your firm's compliance with Title 21 of the Code of Federal Regulations Part 123 (21 CFR §123).

During our inspection, the FDA investigator observed serious deviations in your seafood HACCP program from the requirements listed in the Seafood HACCP Regulation, Section 123.12, Special Requirements for Imported Products. The FDA investigator provided you with a copy of the FDA 483 which represents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. This inspection was also in follow-up to a previous inspection conducted March 26-27, 2003 to verify that corrective actions had taken place for dried oysters. A copy of the FDA 483 was also given to you as a result of that inspection. At the most recent inspection, you informed the investigator that you had not made any of the corrective actions for the dried oysters since the March 26-27, 2003 inspection.

The violations of utmost concern to us are as follows:

1. 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 did not perform an affirmative step for:

Frozen red snapper fillets manufactured by [REDACTED] in [REDACTED]

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 Regulation, to comply with 21 CFR 123.12 (a)(2)(ii), However, your firm did not perform an affirmative step for:

Dried oysters manufactured by [REDACTED] in [REDACTED]

Letter to Mr. Chan, Hung Chong Lung, Inc.

Page 2

These violations indicate that your firm is not complying with FDA's importer verification requirements. These serious deviations from the Seafood HACCP Regulation cause your frozen red snapper fillets and your dried oysters to be adulterated within the meaning of Section 402(a)(4) of the Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly, your seafood products are adulterated in that they may have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

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.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action may include seizure and/or injunction. In addition, FDA may detain your seafood products without examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter of specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

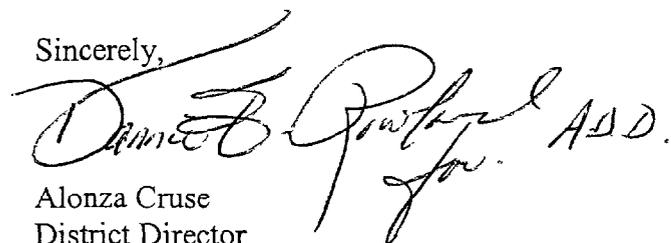
Your written reply relating to these concerns should be directed to:

U.S. Food & Drug Administration
Attn: Director, Import Operations Branch
Los Angeles District
222 West 6th Street, Suite 700
San Pedro, CA 90731

Letter to Mr. Chan, Hung Chong Lung, Inc.
Page 3

If you have questions regarding the implementation of the Seafood HACCP Regulation, you may contact Ruth P. Dixon, Compliance Officer, at (310) 831-6123 extension #155 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

A handwritten signature in cursive script, appearing to read "Alonza Cruse". To the right of the signature, the letters "A.S.D." are written in a similar cursive style. The signature is written in black ink on a white background.

Alonza Cruse
District Director

cc: State of California, Department of Health Services
Food and Drug Branch
601 North 7th Street, MS-357
Sacramento, CA 94234-7320