



DEPARTMENT OF HEALTH & HUMAN SERVICES

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

VIA FEDERAL EXPRESS

December 17, 2001 4165 0463 0259

Our Reference: 2951445

Alfred Y. Kwong, President
Camtrade Enterprises, Inc.
23520 Foley Street, Unit F
Hayward, California 94545

WARNING LETTER

Dear Mr. Kwong:

We inspected your seafood firm on September 20-24 and October 3, 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 deviations. These deviations cause your Fish Sauce, Smoked Round Scad, and Salted Shrimp Fry 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 Mrs. Lourdes C. Kwong, General Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP deviations were 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's performance of affirmative step Option D under 21 CFR 123.12(a)(2)(ii) of maintaining on file a copy, in English, of the foreign processor's HACCP plans

for Smoked Round Scad, Fish Sauce, and Salted Shrimp Fry manufactured by [REDACTED] is inadequate. Specifically,

- (a) You did not obtain written guarantees from your supplier pledging that the imported fishery products were processed in accordance with the Seafood HACCP regulations.
 - (b) The HACCP plan for Smoked Salted Round Scad in vacuum packaging does not address the food safety hazard of *Clostridium botulinum*. Since the Frozen Smoked Salted Round Scad you receive does not have a label that includes a warning that the product must be kept and thawed under refrigerated conditions, the hazard of *Clostridium botulinum* must be included in the processor's HACCP plan.
2. You must adequately monitor sanitation conditions and practices at your facility, to comply with 21 CFR 123.11(b). However, your firm did not monitor the exclusion of pests from your facility with sufficient frequency to ensure control as evidenced by the presence of rodent pellets under pallets throughout the premises.

We observed similar insanitary conditions during the previous inspections of your facility in September 1998 and January 2000. We discussed this GMP deviation with Mrs. Kwong at the conclusion of both inspections, and also reported it by correspondence to you from this office on October 13, 1998. We are concerned that you have not made any effort to correct this problem.

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.

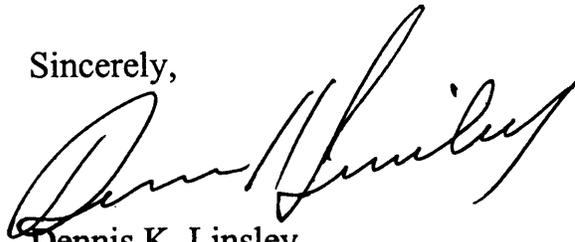
The above-identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. 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 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,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley". The signature is written in a cursive style with a large, looping initial "D".

Dennis K. Linsley
District Director
San Francisco District

Enclosure: FDA 483