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

VIA FEDERAL EXPRESS

Our Reference: 2939586

July 2, 2003

Shawn Cheng, Vice President  
Tak Yuen Corp.  
1973 Davis Street  
San Leandro, California 94577

**WARNING LETTER**

Dear Mr. Cheng:

On May 8 and 9, 2003, the U.S. Food and Drug Administration (FDA) conducted an inspection of your facility located at 1973 Davis Street, San Leandro, California. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (Title 21, Code of Federal Regulations, Part 123—21 CFR 123). A copy of the regulations is enclosed for your ready reference.

We found that you have serious deviations from the regulations cited above. These deviations cause your imported Koon Chun Sauce Factory brand shrimp sauce to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) in that the product has been prepared, packed, or held under insanitary conditions, whereby it may have been rendered injurious to health.

During our inspection, the FDA investigator observed the following deviations:

1. You must have product specifications that are designed to ensure that the 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 a product specification for Koon Chun Sauce Factory brand shrimp sauce imported from [REDACTED].
2. You must implement an affirmative step which ensures that the fishery product 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 Koon Chun Sauce Factory brand shrimp sauce manufactured by Koon Chun Sauce Factory in [REDACTED].

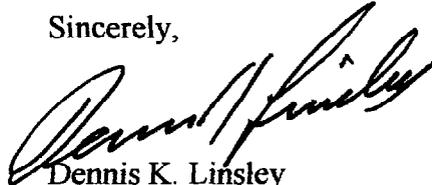
The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

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 includes seizure and/or injunction. In addition, FDA may detain your imported seafood products without examination.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct these violations. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections 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 response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,



Dennis K. Linsley  
District Director

cc: Lucilla Y. Luo, Office Manager