



DEPARTMENT OF HEALTH & HUMAN SERVICES

**Public Health Service
Food and Drug Administration**

m4062r

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

VIA FEDERAL EXPRESS

August 11, 2000

Our Reference: 2954045

Wilson Hui, President
Jimyko, Inc., dba Jameco Company
2190 Army Street
San Francisco, California 94124

WARNING LETTER

Dear Mr. Hui:

We inspected your seafood firm on February 24, 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).

We found that your firm has serious HACCP deficiencies. These deficiencies cause your refrigerated dried shrimp and ready-to-eat dried squid shreds fishery products 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 Mr. Hung N. Lam, General Manager, at the conclusion of the inspection. We are enclosing a copy of the FDA 483 for your reference. Your serious HACCP violations 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, in order to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for dried shrimp and ready-to-eat dried squid shreds from Taiwan.
2. 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 dried shrimp from Taiwan for controlling the food safety hazards of sulfites and color additives.

We observed similar deficiencies during the previous inspection of your facility on September 21, 1998. We discussed these deficiencies with Ms. Theresa Hui, Vice President, at the conclusion of the inspection and also reported them by correspondence to you from this office on December 21, 1998. Our recent inspection showed that your firm has not made the corrections related to the shrimp product.

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, injunction, or detention of future shipments 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,



Mary H. Woleske
Acting Director
San Francisco District