



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

m406/n

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

VIA FEDERAL EXPRESS

August 10, 2000

Our Reference: 2953961

Christopher C. Y. Tan, President
Golden Pacific International, Inc.
1580 Tennessee Street
San Francisco, California 94107

WARNING LETTER

Dear Mr. Tan:

We inspected your seafood firm on February 25 and 28, 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 dried boiled anchovies and dried shaved bonito 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 Ms. Pearl P. Tan, Secretary, 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 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) Dried shaved bonito (from [REDACTED], to ensure control of the food safety hazards of histamine formation, and potential pathogen growth and toxin formation from inadequate drying of the product.

(b) Dried (uneviscerated) boiled anchovies (from [REDACTED]), to ensure control of the food safety hazards of *Clostridium botulinum*, histamine, and pathogen growth and toxin formation from inadequate drying of the product.

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'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 plan and written guarantee for dried shaved bonito manufactured by [REDACTED] is inadequate. The HACCP plan does not list the food safety hazards of pathogen growth and toxin formation from time/temperature abuse and inadequate drying.

We observed similar deficiencies during the previous inspection of your facility on September 23, 1998. We discussed these deficiencies with Ms. Tan, at the conclusion of the inspection and also reported them by correspondence to her from this office on November 13, 1998. Our recent inspection showed that your firm has only made partial corrections.

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 of 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

Enclosure