



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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**VIA FEDERAL EXPRESS**

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

December 4, 2003

Our Reference: CFN 2954627/FEI 1000420881,

Amador A. Remular, Owner  
Philippine Food Distributor  
94-547 Ukee Street, Room 111  
Waipahu, Hawaii 96797

**WARNING LETTER**

Dear Mr. Remular:

We inspected your seafood firm on September 9 and 11, 2003. We conducted this inspection to determine your firm's compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123.

We found that your firm has serious HACCP deviations. These deviations caused your Frozen Smoked Scad and Frozen Milkfish 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 had been prepared, packed, or held under insanitary conditions, whereby they may have been rendered injurious to health. We listed the HACCP deficiencies on a Form FDA 483 and discussed them with you at the conclusion of the inspection. We are enclosing a copy of the Form FDA 483 for your reference. Your serious HACCP deviations 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 Frozen Smoked Scad and Frozen Milkfish imported from the Philippines.
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 Frozen Smoked Scad and Frozen Milkfish imported from the Philippines.

We acknowledge that during the inspection, you provided our investigator with your firm's Importer Written Verification Procedures and Product Food Safety Specifications for Frozen Smoked Scad and Frozen Milkfish. Your Product Food Safety Specifications on both products are not acceptable. There are species and process related hazards associated with these products. You may refer to Chapter 3 of the Fish & Fisheries Products Hazards and Controls Guidance for the associated hazards. Although you submitted your written verification procedures, you did not provide proof that you have performed the Option D affirmative step of obtaining the foreign processor's HACCP plans and written guarantee.

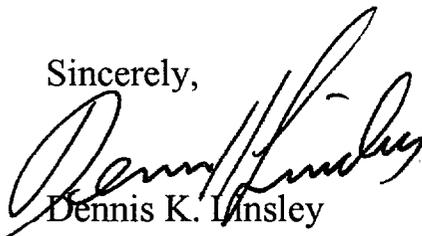
Over two months have elapsed since the FDA inspection. You have had sufficient time to correct the violations. We may initiate regulatory action without further notice if you have not corrected these violations. For instance, we may take further action to seize your products and/or enjoin your firm from 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 recurrence. 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,



Dennis K. Linsley

District Director

San Francisco District

Enclosure: Form FDA 483