



DEPARTMENT OF HEALTH & HUMAN SERVICES

20504

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

VIA FEDERAL EXPRESS

Our Reference: 2954044

December 7, 2001

John Cheung, President/CEO/CFO  
May Food Supply Inc.  
1350 San Mateo Avenue  
South San Francisco, California 94080

**WARNING LETTER**

Dear Mr. Cheung:

On November 5 and 7, 2001, we inspected your seafood processing facility located at 1350 San Mateo Avenue, South San Francisco, California and found that you have serious deviations from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your Dungeness crabs, which are imported from [REDACTED] to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), in that the products have been prepared, packed, and held under insanitary conditions whereby they may be rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your serious HACCP deviations 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 to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for Dungeness crabs imported from [REDACTED]
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 regulations to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for Dungeness crabs exported by [REDACTED]

We observed the above-mentioned HACCP deviations during two previous FDA inspections of your facility in November 1998 and August 1999. We discussed your deviations by correspondence dated January 20, 1999. A copy of 21 CFR 123, Fish &

Fishery Products, is enclosed for your ready reference. We recommend that you review 21 CFR 123.12, *Special requirements for imported products*.

During the current inspection, we discussed with you the following deviations from the Current Good Manufacturing Practices, 21 CFR 110:

- Accumulated debris and old equipment clutter that were observed in several areas of the facility which needed to be removed and the areas cleaned.
- Rusted ice machine pipe in one of the coolers.
- Dripping water from a light fixture in a second cooler.
- Need for cleaning and sanitation of the second cooler because of off odors.

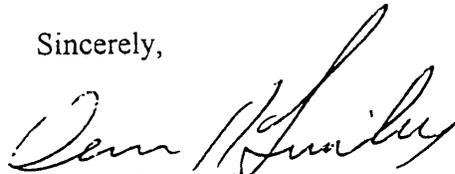
At the conclusion of the inspection, the seafood deviations were listed on Form FDA 483 (Inspectional Observations) and discussed with Raymond C. Chang, Manager. A copy of this form is enclosed for your ready reference. This list is not meant to be an all-inclusive list of violations. It is your responsibility 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.

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, 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 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  
San Francisco District