



VIA FEDERAL EXPRESS

WARNING LETTER

FLA-01-12

November 13, 2000

Eduardo R. Hernandez, President
Ocean Five, Incorporated
7850 NW 72nd Avenue
Medley, Florida 33166

Dear Mr. Hernandez:

On June 5 and 6, 2000, the Food and Drug Administration (FDA) conducted an inspection of your seafood importing and repacking facility located at 7850 NW 72nd Avenue, Medley Florida 33166. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practices (GMP) requirements for foods (21 CFR 110).

During our inspection, we observed serious deviations from the principles of HACCP and the significant requirements of the program. The investigator provided you with copies of the Domestic Seafood HACCP Report (form FDA 3501), Import Seafood HACCP Report (form FDA 3502), and the Inspectional Observations (form FDA 483) which presents his evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

Domestic HACCP Program

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for cooked stone crab claws to control the food safety hazard of pathogen growth and toxin formation.

Import HACCP Program

You must have and implement written specifications for the seafood products you import, which list all of the appropriate safety hazards and limits to comply with 21 CFR 123.12(a)(2)(i). However, no written specifications have been established.

You must implement an affirmative step which ensures that the fish and fishery product(s) you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm performed an affirmative step of maintaining on file a copy of the foreign processor's HACCP plan and written guarantee for imported fish products, such as yellow tail and grouper, manufactured by [REDACTED] that was not adequate in that your firm does not maintain on file a copy, in English, of the HACCP plan and written guarantee.

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.

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. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

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 reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding the implementation of the HACCP Regulations, please contact Mr. Hester at (407) 475-4730 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,



Emma R. Singleton
Director, Florida District