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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley PL, Ste. 200
Maitland, FL 32751

WARNING LETTER

FLA-01-78

August 13, 2001

Robert G. Couto, President
Ocean Fresh Seafood, Inc.
473 East Washington Street
North Attleboro, Massachusetts 02760

Dear Mr. Couto:

We completed an inspection of your seafood importing facility, located at 8051 N.W. 36th Street, Suite 601, Miami, Florida, on April 26-27, 2001 and found that you continue to have serious deviations from the seafood processing (HACCP) regulations (21 CFR 123). These deviations cause your imported fresh refrigerated escolar, tuna and other fish and fishery products imported from Ecuador to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood processing (HACCP) regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

You must have written product safety 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 written product specifications for fresh refrigerated escolar, tuna and all other fish and fishery products imported from Ecuador. This deviation was previously brought to your attention in our letter of November 22, 1999.

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 fresh escolar manufactured by [REDACTED]. In addition, your firm performed an affirmative step for fresh tuna manufactured by [REDACTED] that is inadequate in that the HACCP plan on file does not list scombrototoxin (histamine) as a hazard associated with fresh tuna. This deviation was also previously brought to your attention in our letter of November 22, 1999.

In addition, the HACCP plans on file from [REDACTED] and [REDACTED] [REDACTED] have not been reassessed for adequacy in over a year.

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 from your 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: Magda M. Karlsen, Compliance Officer, 6601 Northwest 25th Street (P.O. Box 59-2256) Miami, Florida 33159-2256. If you have questions regarding the implementation of the seafood processing (HACCP) regulations, you may contact Mrs. Karlsen at 305-526-2800, extension 921, for the answers and/or directions towards guidance and sources of training in achieving compliance.

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

Sincerely,



 Emma R. Singleton
Director, Florida District