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VIA FEDERAL EXPRESS

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

Ref: Customs Entry No. WKV-0028144-9
Products: Fresh Mahi-Mahi

WARNING LETTER

FLA-00-59

June 6, 2001

Roberto Alvarez, President
Pacific Ocean Seafood
7304 N.W. 34th Street
Miami, Florida 33122

Dear Mr. Alvarez:

The Food and Drug Administration (FDA) attempted to examine a shipment of snapper offered for entry into the United States by your firm on April 7, 2001, under the above referenced entry number, and found that the entire shipment was not available for FDA examination. Title 21, Code of Federal Regulations (21 CFR), Section 1.90 requires the importer to hold the entire entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. Since the entry was not held intact, we have requested the U. S. Customs Service (Customs) to order redelivery of the entry that has been distributed without a release from FDA.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of further shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter outlining the specific steps you have taken to correct the violation. Your response should include an explanation of each step being taken to prevent the recurrence of the violation. In the event that the product is still available for examination, you should inform Customs and FDA if and when redelivery is accomplished.

Your written reply should be addressed to the Food & Drug Administration, Attention: Carlos W. Hernandez, Compliance Officer, P. O. Box 59-2256, Miami, Florida 33159-2256.

Sincerely,

Kendall W. Suster

gsr Emma R. Singleton
Director, Florida District

cc: International Cargo Brokers, Inc.
1776 N.W. 95th Avenue
Miami, Florida 33172

Thomas Winkowski
Port Director
U. S. Customs Service
P. O. Box 02-580
Miami, Florida 33102-5280