



**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

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

WARNING LETTER

FLA-03-45

September 11, 2003

Karl H. Castedo, General Manager
Dimarsa International LLC
9600 N.W. 25th St., Ste.- 3B
Miami, FL 33172

Dear Mr. Castedo,

On May 6-7, 2003, the Food and Drug Administration (FDA) conducted an inspection of your facility located at the above address. The inspection was conducted to determine your firm's compliance with FDA's seafood processing regulations (21 CFR 123).

During our inspection, the FDA investigator observed serious deviations from the Seafood HACCP regulations. The FDA investigator discussed and issued to you, form FDA-483 which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

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 a product specification for fresh tuna imported from [REDACTED]

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 fresh tuna manufactured by [REDACTED] in [REDACTED]

The above identified deviations are not intended to be 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: Carlos W. Hernandez, Compliance Officer, Food and Drug Administration, 6601 Northwest 25th Street, Room 241, Miami, Florida 33122. If you have questions regarding the implementation of the HACCP Regulations, you may contact Mr. Hernandez at 305-526-2800, ext. 941, for the answers and/or directions towards guidance and sources of training in achieving compliance.

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

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton", with a long horizontal flourish extending to the right.

Emma R. Singleton
Director, Florida District