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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-0~~7~~⁴-09

October 27, 2003

Peter L. Silver, President
Macro Seafood, Inc.
1401 La Costa Drive East
Pembroke Pines, Florida 33027

Dear Mr. Silver:

On May 30, 2003 and June 2, 2003, the Food and Drug Administration (FDA) conducted an inspection of your seafood import operation located at the above address in Pembroke Pines, Florida. The inspection was conducted to determine your firm's compliance with FDA's Seafood HACCP Regulations (21 CFR 123). The Seafood HACCP regulations were issued pursuant to Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Seafood that is processed in violation of the HACCP regulations is adulterated, according to the Act, because it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or may have been rendered injurious to health. You can find the Act, the Seafood HACCP regulations, and FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition through links in FDA's home page at <http://www.fda.gov>.

During our inspection, the FDA investigator observed a shortcoming in your import verification procedures that deviates from the requirements of the Seafood HACCP regulations. The investigator also provided you with a list of Inspectional Observations (Form FDA 483), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observation of concern to us is as follows:

You must implement affirmative steps to ensure 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, in English, of the foreign processor's HACCP plan and Letter of Guarantee for frozen IQF lobster manufactured by [REDACTED] that is not adequate.

We acknowledge receipt of your written response to the FDA 483, dated June 11, 2003. In your response, you enclosed your firm's written product specifications and a written guarantee from [REDACTED]

However, the document previously supplied as a HACCP plan by your foreign supplier is inadequate because it fails to meet the requirements for a HACCP plan in Part 123. Specifically, the document, entitled "Standard Operation Procedure," does not include the necessary components of a HACCP plan, such as critical control points, monitoring procedures/frequencies, and verification procedures. As an importer, FDA expects you to be able to identify shortcomings with HACCP plans supplied by your foreign processors (e.g., the omission of hazards or critical components of a HACCP program).

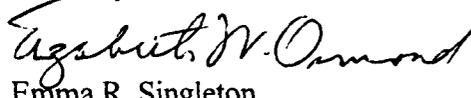
The above identified deviation is not intended to be an all inclusive list of deficiencies. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct this deviation. Failure to promptly correct this deviation 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 deviations, 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: Brant M. Schroeder, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, you may contact Mr. Schroeder by telephone at (407) 475-4763.

Sincerely,

for 
Emma R. Singleton
Director, Florida District