



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

HFI-35

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**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

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

**WARNING LETTER**

**FLA-04-05**

October 21, 2003

Carlos F. Garcia, General Manager  
Tuna Fresh, Incorporated  
11277 NW 81<sup>st</sup> Street  
Miami, Florida 33150

Dear Mr. Garcia:

On August 4-5, 2003, the Food and Drug Administration (FDA) conducted an inspection of your seafood import operation, located at the above address. The inspection was conducted to determine your firm's compliance with FDA's Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). You may find the Seafood HACCP Regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

During our inspection, the FDA investigator observed violations of the special requirements for imported products in 21 CFR 123.12. 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 observations of concern to us are as follows:

You must have written 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 has no written product specifications for any seafood products you import. For example, tuna imported from [REDACTED], this same deviation was previously brought to your firm's attention in our letter of January 13, 2000.

You must maintain records, in English, that document the performance and results of the affirmative steps chosen by your firm, to comply with 21 CFR 123.12(c). However, your firm had no documentation to show that any of the six (6) affirmative steps available in 21 CFR 123.12(a)(2)(ii)(A)-(F), for compliance with 21 CFR 123.12(a)(2), were taken by your firm with regard to any fish and fishery products imported by your firm. For example, option D, authorizes maintaining on file copies, in English, of each foreign processors HACCP plan and written guarantees from each

foreign processor that the imported fish or fishery products were processed in accordance with the Seafood (HACCP) Regulations. This same deviation was previously brought to your firm's attention in our letter of January 13, 2000.

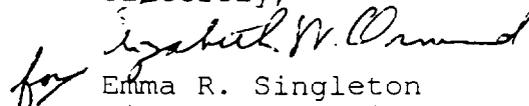
The deviations identified above are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products imported, processed and distributed by your firm are in compliance with the Food, Drug, and Cosmetic Act (the Act) and all requirements of the applicable federal regulations.

These deviations cause your imported fish and fishery products, including your imported tuna, to be adulterated within the meaning of Section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4). You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated without further informal notice. Such actions may include the initiation of a seizure action against your products and/or an action to enjoin your firm from operating. In addition, FDA may detain your seafood imports without physical examination. Under such conditions, FDA will not issue any Certificates for Export or European Union Health Certificates for any fish and fishery products imported by your facility that you plan to export.

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: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, you may contact Mr. Walthall by telephone at (407) 475-4731.

Sincerely,

  
Emma R. Singleton  
Director, Florida District