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**VIA FEDERAL EXPRESS**

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

**WARNING LETTER**

**FLA-02-34**

March 26, 2002

Mark A. Twinam, President and Owner  
Twinam Enterprises, Inc.  
d/b/a T.W. Wholesale  
13613 Gulf Blvd.  
Madeira Beach, Florida 33708

Dear Mr. Twinam:

We inspected your firm, located at 13613 Gulf Blvd., Madeira Beach, Florida 33708 on February 5, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention, cause your scombroid species fish, such as Amberjack and Mahi-Mahi, to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviation is as follows:

To comply with 21 CFR 123.6(b), you must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur. However, your firm does not have and has not implemented a HACCP plan for scombroid species to control the histamine formation hazard. Specifically, the "model" HACCP plan you believe you obtained from one of your competitors was not modified to reflect your firm's actual operations. It also fails to bear any firm or product identifiers, is not signed or dated and has not been implemented. You acknowledged to our investigator that your firm had not conducted a hazard analysis or completed development of a HACCP plan for scombroid species fish. This deviation was previously brought to your attention in our letter dated October 19, 2000.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a HACCP plan consistent with your firm's operations, monitoring or sanitation records and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Ste. 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,



 Emma R. Singleton  
Director, Florida District