



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751

Telephone: 407-475-4700  
FAX: 407-475-4769

**VIA FEDERAL EXPRESS**

**WARNING LETTER**

FLA-01-66

July 3, 2001

K. Scott Hume, President  
Frenchy's Seafood Company  
419 East Shore Drive  
Clearwater, Florida 33767

Dear Mr. Hume:

We completed an inspection of your seafood processing plant, located at the above address, on May 23, 2001 and found that you continue to have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh refrigerated scombrotxin forming fish products such as mahi-mahi and tuna and your smoked fish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for scombrotxin forming fish species such as mahi-mahi and tuna to control the food safety hazard of scombrotxin (histamine) formation.

You must implement the record keeping system listed in your HACCP plan for smoked fish, to comply with 21 CFR 123.6(c)(7). However, your firm is not recording the actual monitoring observations for cook temperature and time and internal temperature and time at the smoking critical control point, or the cooling down temperature and time at the cooling after smoking critical control point, to control the food safety hazard of *C. botulinum* toxin formation. Check boxes are being used in lieu of recording the actual temperatures and times observed.

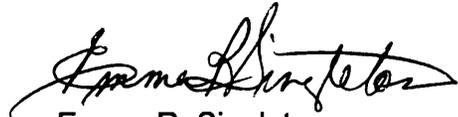
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

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

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 copies of your HACCP plans, monitoring records or 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 your delay and state when you will correct any remaining deviations.

Please send your reply 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, please contact Mr. Walthall at (407) 475-4731.

Sincerely,

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

Emma R. Singleton  
Director, Florida District