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

**VIA FEDERAL EXPRESS**

**WARNING LETTER**

**FLA-01-17**

December 11, 2001

Virginia Morton, President  
Jug Creek Fish Company  
16498 Tortuga Street  
Bokeelia, Florida 33922

Dear Ms. Morton:

We inspected your fish processing facility located at 16498 Tortuga Street, Bokeelia, Florida, on October 10, 2001. The inspection found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). The deviation, which was previously brought to your attention, causes scombroid fish (jack crevalle and fresh mackerel) 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:

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 scombroid species of fish to control the food safety hazard of histamine formation.

We previously sent you an Untitled Letter dated March 6, 1998, which listed the failure of your firm to have a HACCP plan for scombroid fish. We replied on April 16, 1998 to your March 23, 1998 response, advising you of the inadequacies of your response. A copy of the Untitled Letter and our April 16, 1998 response letter is enclosed for your reference.

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 of your HACCP plan for scombroid species of fish 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 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 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: Timothy J. Couzins, Compliance Officer, 555 Winderley Place, Ste. 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Couzins at (407) 475-4728.

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

Enclosures