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VIA FEDERAL EXPRESSFood and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751WARNING LETTER

FLA-02-30

February 13, 2002

John C. Valenti, President  
Bay Island Fish Company  
500 N.E. 185<sup>th</sup> Street, Bay #8  
Miami, Florida 33170

Dear Mr. Valenti:

We inspected your seafood processing plant, located at the above address, on March 14, 2001 and found that you continue to have serious deviations from the Seafood HACCP Regulations (21 CFR Part 123). We regret the delay in our review and evaluation of the inspectional findings. The deviations documented during our inspection cause your fresh refrigerated scombrotoxin forming fish products such as wahoo 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:

Domestic

You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for fresh histamine producing fish fails to list a critical limit for the adequacy of ice or other cooling media at the receiving critical control point. In addition, your plan lists temperature critical limits of [REDACTED] F at the receiving critical control point and [REDACTED] F at the storage critical control point that are not adequate to control the hazard of histamine formation. Temperature checks alone at receiving are not sufficient to control the histamine hazard and the recommended critical limit for storage of histamine producing fish is 40° F or storage under ice.

You must list a monitoring frequency for each critical limit that must be met, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for fresh histamine producing fish does not list monitoring frequencies at the receiving and storage critical control points to control the hazard of histamine formation. For example, your plan must include monitoring frequencies to check every lot received for adequate ice, and cooler temperature must be monitored continuously or stored product checked for adequate ice at least twice daily.

Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, the corrective actions listed in your HACCP plan for fresh histamine producing fish at the receiving and storage critical control points are inadequate to control the hazard of histamine formation. For example, your plan states corrective action will be taken if the temperature exceeds [REDACTED] F at receiving and [REDACTED] F at storage. Histamine toxin can form at any temperature above 40° F. In addition, no corrective action is listed regarding the lack of adequate ice or other cooling media at receiving or storage.

### Imports

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 does not have adequate written product specifications for fish imported from Honduras to address the food safety hazard of histamine formation that is reasonably likely to occur. Written product specifications for imported seafood products should be designed to ensure the products are safe, free of adulteration, and are processed under sanitary conditions. Your firm's description of products, identification of species, and purchase specifications are inadequate to serve as written product specifications for imported products.

You must fully implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However your firm does not have a current letter of guarantee to accompany the foreign processors HACCP plan for [REDACTED]

Information and guidance for controlling histamine formation can be found in Chapter 7 of the FDA Fish & Fishery Products Hazards & Controls Guidance, *Third Edition, June 2001*.

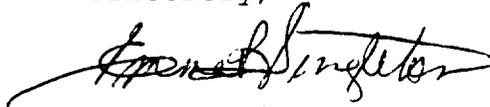
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your seafood products and/or enjoin your firm from operating.

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 revised HACCP plan, monitoring records, written guarantees for imported products, 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 cursive script, appearing to read "Emma R. Singleton". The signature is written in black ink and is positioned above the typed name.

Emma R. Singleton  
Director, Florida District