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

WARNING LETTER

FLA-02-42

May 21, 2002

VIA FEDERAL EXPRESS

Randy W. LaPenta, President
Southcoast Fish Company, Inc.
999 South Dixie Hwy, West
Pompano Beach, Florida 33060

Dear Mr. LaPenta:

We inspected your firm at the above address on February 13 and 14, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fresh Tuna, Mahi Mahi, and Wahoo (all three are Scombrotoxin-forming fish) to be adulterated in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. Section 342(a)(4). You can find this Act and these regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

1. 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). Your firm does not have a HACCP plan for fresh Tuna, Mahi Mahi, and Wahoo to control the reasonably-likely-to-occur food safety hazard of Scombrotoxin formation.
2. You must 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 did not perform an affirmative step for Mahi Mahi imported from your foreign processors in Costa Rica and Ecuador. Your firm failed to have a copy of any foreign supplier's HACCP plans and a written guarantee for seafood products that you import from Costa Rica and Ecuador.

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 U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products 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 amended HACCP plans, monitoring records, revised forms, 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: Diane Englund, Compliance Officer, 555 Winderly Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma Singleton", with a long horizontal flourish extending to the right.

Emma Singleton
District Director
Florida District Office