

VIA FEDERAL EXPRESSg3535d
Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751WARNING LETTER

FLA-02-60

September 12, 2002

Cecil C. Lane, President and Co-Owner
Southern Star Seafood Inc.
2350 Old Dixie Highway
Ft. Pierce, Florida 33946

Dear Mr. Lane:

We inspected your firm, located at 2350 Old Dixie Highway, Ft. Pierce, Florida 33946 on June 17, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your scombroid species fish, such as Mackerel and Bluefish, to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders your seafood products adulterated within the meaning of Section 402(a)(4) of the Act. Accordingly your scombroid species fish are adulterated, in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 through links in FDA's home page at <http://www.fda.gov>.

The deviations are as follows:

1. You must implement the record keeping system that you listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the Storage critical control point to control histamine formation as listed in your HACCP plan for scombroid species. Your plan states that you will monitor the adequacy of the ice surrounding your product twice daily.

Note: Your plan also provides that, in addition to monitoring the ice, you will monitor the cooler temperature twice daily. Checking the cooler temperature twice daily is considered an inadequate procedure for controlling histamine formation; however, checking the cooler temperature is not necessary here since you are monitoring the ice.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with CFR 123.6(c)(3). However, your firm's HACCP plan for scombroid species does not list a critical limit at the Receiving critical control point to control the hazard of histamine.

- (a) You must include a method of assuring that the scombroid species purchased by your firm are handled in a safe manner prior to receipt by your firm. FDA suggests either requiring harvest vessel records from the fishing vessels or conducting histamine testing on a representative number of fish (same species) in each lot. Your firm appears to receive records from harvest vessels that document the harvest methods and conditions used by those ships. Reviewing Chapter 7 of the FDA Fish & Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 (pages 88-89) can help you determine if these records include the appropriate information.
- (b) In addition to temperature checks and harvest vessel records, you should also include a critical limit and monitoring procedures for sensory examinations. FDA suggests rejecting a lot or conducting histamine testing if the percentage of decomposition in a lot exceeds 2.5 percent.

Moreover, the monitoring procedure for internal temperature checks described to our Investigators during our inspection is inadequate to control the safety hazard of histamine formation. Specifically, the sample size of one fish is not representative of a lot for determining adequate internal temperatures at the Receiving critical control point.

Your firm submitted HACCP plans with a cover letter dated January 23, 2001, as a proposed corrective action plan in response to a previous FDA inspection and consequential correspondence. We have attached copies of the HACCP plans for your reference. Although your firm did not supply our investigators with a copy of the first page of your scombroid species HACCP plan, based on the monitoring procedures implemented by your firm, we are assuming that you are currently using the controls, including the Receiving critical control point, which are listed in that plan. Please verify, in your response to this letter, that you are indeed using these controls.

In addition, your firm established HACCP plans by grouping types of fish processed for a specific food safety hazard. As our letter dated December 28, 2000 stated, the HACCP regulation 21 CFR 123.6 (b) (2) provides for grouping types of fish if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed are identical for all of the fish. However, our review of your HACCP plans noted that some of your fish products have multiple food safety hazards. For example, Jack, Blue Runner and Spanish Mackerel have the food safety hazards of ciguatoxin and histamine formation. We suggest you review and revise your HACCP plans to establish a HACCP plan for each appropriate group of fish and specify what specific fish apply to each group.

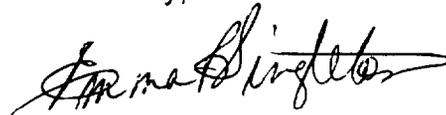
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You may wish to include in your response documentation such as revised HACCP plans, 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, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

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

cc: James E. Lane
Secretary Treasurer/Co-owner