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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-98

September 8, 2000

Charles Morgan, president /owner
Harbor Docks, Inc.
538 Highway 98 East
Destin, FL 32541

Dear Mr. Morgan:

We inspected your firm, located at 538 Highway 98 East, Destin, FL on February 14-16, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your scombroid species fish 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.

The deviations were as follows:

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 scombroid fish lists a critical limit at the receiving critical control point that is not adequate to control the histamine hazard. In addition to the critical limit listed in your HAACP plan, "Internal temperature of fish must be 40 degrees F or less at time of receiving", the critical limit needs to include:

- a. For product received by truck, the critical limits should also include documentation of temperature control at or below 40 degrees F during transit or adequate ice on the product at the time of receipt.
- b. For product received by boat directly from fishermen, the receiving critical limits should also include parameters for harvest vessel records and/or histamine testing and sensory evaluations. After revising your critical limits, you will also need to revise your monitoring procedures at the receiving critical control point to include monitoring of the additional critical limits.

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at both the receiving and storage critical control points to control histamine listed in your HACCP plan for scombroid species fish. Your firm received scombroid species on 1/15/00, 2/1/00, 2/9/00 and 2/11/00, but did not prepare any monitoring records. Also, your firm failed to maintain any storage monitoring records for 2/12/00 and 2/14/00 and only partial storage monitoring records for 8/16-22/99.

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, your corrective action plan for scombroid fish at the storage critical control point to control the histamine hazard is not appropriate, as it does not address the disposition of fish that are determined to be adulterated after they are held and evaluated due to a critical limit deviation.

You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the exclusion of pests and prevention of cross contamination with sufficient frequency to ensure control as evidenced by:

Over twenty live flies and one hundred dead flies observed in the processing room during operations.

Over thirty live pelicans and one dead pelican observed outside the processing area during the inspection.

Pelicans and pelican droppings were observed at the entranceway to the processing area. Employees were observed to routinely drag containers filled with seafood along the loading dock floor directly over the pelican droppings, then nest some of these containers on top of other containers filled with seafood products in the walk-in cooler.

Pelicans were observed to stand on the edge of trashcans, which employees routinely handled, then handle seafood products without washing and sanitizing their hands.

Employees in the processing area routinely handled various insanitary objects, then resumed handling or processing products without washing and sanitizing their hands.

You must maintain sanitation control records to document the monitoring and correction of sanitation conditions and practices during processing to comply with 21 CFR 123.11(c). However, no sanitation control records were prepared on February 14 or prior to processing on February 15. Six of the twelve items listed on your sanitation control form for January 3 and 5 and five of the twelve items on sanitation control form for January 4, 2000 were not recorded.

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, such as a revised HACCP plan and revised 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 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: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Hester at (407) 475-4730.

Sincerely,

A handwritten signature in black ink, appearing to read "Emma R. Singleton". The signature is fluid and cursive, with a large initial "E" and "S".

Emma R. Singleton,
Director, Florida District