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Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, FL 32751VIA CERTIFIED MAILWARNING LETTER

FLA-03-07

October 29, 2002

Stuart R. MacNiven, Vice President
Hurricane Seafood, Inc.
7945 NW 64th Street
Miami, Florida 33166

Dear Mr. MacNiven:

We inspected your firm at the above address on April 23 and 24, 2002, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). The deviations cause your fresh H&G Mahi Mahi; vacuum-packaged raw, refrigerated Mahi Mahi fillets; and cooked stone crab claws 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 fresh H&G Mahi Mahi; vacuum-packaged raw, refrigerated Mahi Mahi fillets, and cooked stone crab claws 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 homepage at <http://www.fda.gov>.

The deviations are as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and 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(a) and (b). However,
 - Your firm does not have a HACCP plan for vacuum-packaged raw, refrigerated Mahi Mahi fillets to control the food safety hazards of *Clostridium botulinum* growth/ toxin formation and Scombrototoxin (histamine) formation.
 - Your firm does not have a HACCP plan for cooked stone crab claws to control the food safety hazard of pathogen growth and toxin formation due to time and temperature abuse.

2. 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 Mahi Mahi lists a critical limit, "Product Temp Receiving [REDACTED] MAX" at the "Receiving" critical control point, and a critical limit, "Product Temperature [REDACTED] MAX" at the "Storage" critical control point that are not adequate to control Scombrototoxin (histamine) formation. A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."

As a secondary processor (warehouse) at your "Receiving" critical control point you should ensure that fresh histamine forming fish are delivered under ice or cooling media, with an adequate quantity of ice or cooling media at the time of delivery to completely surround the product, or that they are received with records documenting that the fish were held at or below 40°F throughout transit. In addition, at the "Storage" critical control point refrigerated fresh fish should be stored at or below 40°F or covered in ice or other cooling media. Refer to Chapter 7 of the FDA Fish & Fisheries Products Hazards and Controls Guidance, Third Edition, June 2001 (pages 88-90) for information on critical limit recommendations at the Receiving and Storage critical control points.

3. 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 Mahi Mahi at the "Receiving" critical control point to control Scombrototoxin (histamine) formation is not appropriate. In the absence of transportation records or when your critical limit has been violated, you should not only reject the lot, but you should also discontinue the use of the supplier or carrier until evidence is obtained that the transportation practices have changed.
4. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records for the safety of water that comes into contact with food or food contact surfaces and the safety of water used to make ice. These records are especially important for high risk ready-to-eat products, such as your cooked stone crab claws.

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.

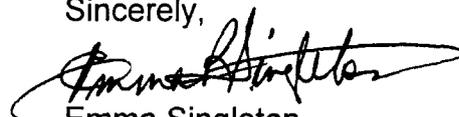
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products and/or enjoin your firm from operating. Under such conditions, the FDA will not issue any Certificates for

Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the 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 J. Englund, Compliance Officer, 555 Winderley 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