DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD

January 11, 2012

Mr. Xue Jun Du
Managing Director
Golden Ocean Fish Ltd
33 Freeston Road, Walu Bay
GPO Box 13596
Suva, Fiji

Dear Mr. Du:

We inspected your seafood processing facility, Golden Ocean Fish Ltd., located at 33 Freeston Rd, Walu Bay, Suva, Fiji on August 8-10, 2011. Upon further review of our investigator's inspection report and findings during the inspection, we determined that you have serious violations of the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 and the Current Good Manufacturing Practice.

In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C.§342(a)(4). Accordingly, your firm's scombrotoxin (histamine) forming species of fish appear to be adulterated, in that the products have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health. At the conclusion of the inspection, the FDA investigator issued a FDA-483, Inspectional Observations, listing the deviations found at your firm.

The seafood HACCP regulation requires that you implement a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP involves:

- Identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and

- Having controls at each "critical control point" in the processing operation to eliminate or minimize the likelihood that the identified hazard will occur.

HACCP provides a systematic way to identify, implement, and document those measures that demonstrate to FDA, to your customers, and to consumers that you are routinely practicing food safety by design. During our review of your plan, we found shortcomings that are violations of the seafood HACCP regulation.

We acknowledge your firm's response dated August 15, 2011 to the FDA 483 issued to your firm on August 11, 2011. However our review revealed that the response was not adequate, as further described in this letter.

You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

We note the following serious deviations from the requirements of the Seafood HACCP regulation:

1. You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (l). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's revised HACCP plan provided in your August 15th response entitled "Fresh, raw Loin, Fillet Whole G&G, H&G Frozen, raw whole round G/G &H/G" does not list the food safety hazard of pathogen growth. Specifically, the plan lists an intended use for some of the fishery products as "(b)(4) " Consequently, pathogen growth is a reasonably likely hazard because the products will not receive a cook prior to consumption.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR l23.3(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." However, your firm's revised HACCP plan provided in your August 15th response entitled "Fresh, raw Loin, Fillet Whole G&G, H&G Frozen, raw whole round G/G &H/G" , intended for your scombrotoxin (histamine) forming species of fish, lists critical limits that are not adequate to control histamine development. Specifically the plan lists "(b)(4) ..." critical control point; and lists "(b)(4) " critical control point. These critical limits are not adequate to control histamine because they do not include any specific "temperature" values. FDA recommends that in order to control histamine development, temperatures should be maintained at or below 40°F.

3. You must have a HACCP plan that, at a minimum, lists monitoring procedures and their frequency for each critical control point, to comply with 21 CFR 123.6(c)(4). However your firm's revised HACCP plan provided in your August 15th response lists (b)(4) ..." critical control point that is not adequate to control histamine. Specifically, your firm lists that (b)(4) ." FDA

recommends that firms measure a minimum of 12 fish, unless there are fewer than 12 fish in the lot, in which case measure all of the fish.

4. Because you chose to include a corrective action plan in your HACCP plan, your described corrective action must be appropriate, to comply with 21 CFR 123.7(b). However your corrective action plan listed in your HACCP plan provided in your August 15th response at the "Receiving at fresh plant..." critical control point to control histamine (i.e., in the (b)(4) of the critical control point) is not appropriate. Specifically, your firm's corrective action fails to include histamine testing on a minimum of 60 fish when the lot fails the sensory evaluation. In addition, your firm's corrective action at the Cooler Storage (CCP5) lists actions that are not appropriate. FDA recommends your corrective actions for a product involved in a critical limit deviation include chilling and holding the product until it can be evaluated based on its total time and temperature exposure, including exposures during prior processing operations.

Additional comments:

During discussion with your firm, it was noted that your firm performs histamine testing on a composite sample with a critical limit of (b)(4) ppm. Your firm was advised that FDA recommends reducing the critical limit when compositing samples and that your firm needs to reduce the critical limit to 17 ppm for your composite samples. Your firm corrected this in the revised plan however completed monitoring records submitted by your firm lists histamine operating limits of 17 and (b)(4) ppm. FDA recommends the firm should identify the number of fish in each composite associated with the 17 ppm critical limit. The monitoring records do not reflect how many fish were sampled.

FDA was unable to evaluate your firm's monitoring and corrective actions for the "Sensory & Temperature Checks (CCP3)". Please clarify and/or further explain this critical control point (i.e., whether it is part of receiving, processing storage or possibly shipping).

For additional information regarding FDA's recommended controls for the hazards and controls discussed above, please refer to Chapters 7 of the Fish and Fisheries Products Hazards and Controls Guidance: Fourth Edition, which can be found on FDA's website at:

http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/index.htm

You should respond in writing within thirty (30) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as a copy of any revised HACCP plans, at least five (5) product days worth of monitoring records to demonstrate that you have implemented the revised plan and other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before the 30 days, you should explain the reason for your delay and state when you will correct any remaining violations.

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 and the Seafood HACCP regulation. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Food and Drug Administration, Attention: Standra Purnell, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Manufacturing and Storage Adulteration Branch HFS-607, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Standra Purnell via email at standra.pumell@fda.hhs.gov.

Sincerely,

/s/

Kathleen Lewis, J.D.
Acting Division Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition