DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

December 4, 2013

Mr. Ko Shun Jung
Managing Director
Ggc Twn. Co. Ltd.
6/14 Moo1 Rasada Moung Phuket 83000
Muang Phuket, Thailand

Reference No. 416272

Dear Mr. Ko Shun Jung:

We inspected your seafood processing facility, Ggc Twn. Co. Ltd., located at 6/14 Moo 1 Rasada Moung Phuket 83000 Muang Phuket, Thailand, on May 20-21, 2013. During the inspection, we found that you had serious violations of the Seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). At the conclusion of the inspection, FDA issued a FDA-483, Inspectional Observations, listing the deviations found at your firm. We acknowledge receipt of your response sent via email on June 24, 2013, that included written corrective actions; a revised HACCP plan for your scombrotoxin (histamine) forming fish dated May 23, 2013; and completed monitoring records. We have assessed the response and have continuing concerns as further described in this letter.

In accordance with 21 CFR 123.6(g), failure of a processor of fish and 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 scombrotoxin (histamine) forming fish are adulterated, in that they have been prepared, packed, or held under conditions whereby they may have been rendered injurious to health.

You may find the Act, the Seafood HACCP regulation and the 4th Edition of the Fish and Fisheries Products Hazards and Control Guidance (the Hazard Guide) through links in FDA's homepage at www.fda.gov. The Hazards Guide can be found on our web site at: http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Seafood/FishandFisheriesProductsHazardsandControlsGuide/default.htm.

Based on the inspectional findings and the response to those findings, we have the following concerns.

1. 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 for scombrotoxin (histamine) forming fish dated May 23,2013, lists monitoring procedures or frequencies that are not

adequate to control scombrotoxin (histamine). Specifically, at the (b)(4) critical control point your plan

a. lists (b)(4) ; however, it is unclear whether your firm is monitoring all of the fish in lots that consist of less than (b)(4) . FDA recommends that firms test a minimum of 18 fish, collected representatively throughout each lot; or the entire lot when there are fewer than 18 fish in the lot. FDA further recommends that each lot consist of a single species of fish and that firms reject the entire lot if any fish are found to contain histamine greater than the critical limit listed in the plan for histamine (i.e., for example (b)(4) or (b)(4) .

b. lists (b)(4) However, it is unclear whether your firm is taking internal temperature of every fish at offloading from the harvest vessel. FDA recommends firms measure the internal temperature of a representative number of the largest fish in each lot, concentrating on any that show signs of mishandling. For example, when receiving 10 tons or more of fish, FDA recommends measuring a minimum of one fish per 1000 pounds. For smaller amounts, FDA recommends measuring a minimum of 12 fish, unless there are fewer than 12 fish in the lot in which case all of the fish should be measured. Firms should select fish randomly from throughout the lot.

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 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." However, your firm's HACCP plan for scombrotoxin (histamine) forming fish does not list critical limits associated with the number of fish your firm analyses for the (b)(4) at the (b)(4) critical control point. FDA recommends that firms examine at least 118 fish collected representatively throughout each lot; or the entire lot for lots smaller than 118 fish.

3. Because you chose to include a corrective action plan in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However your corrective action at the (b)(4) critical control point plan does not include corrective actions when histamine testing fails. FDA recommends rejecting the entire lot when the histamine exceeds the listed critical limit (i.e., (b)(4) or (b)(4)).

FDA is also requesting clarification of a statement in your HACCP plan. At (b)(4) critical control point, your plan references fish sensory check as (b)(4) FDA could not determine

what (b)(4)[redacted]. Please provide clarification as to what (b)(4)[redacted] represents in your HACCP plan.

You should respond in writing within 30 working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. More specifically, your response should include documentation reflecting the changes you made, such as a copy of your revised HACCP plan or plans, five (5) consecutive days of completed monitoring records (i.e., records for the production of 5 production date codes of the products) to demonstrate implementation of the plan or plans, and any additional information that you wish to supply that provides assurance of your intent to fully comply now and in the future with the applicable laws and regulations. Submission of the information in English will assist in our review. If you cannot complete all corrections before 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 all applicable regulations, including the Seafood HACCP regulation, and the Good Manufacturing Practice regulation (21 CFR 110). 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, Food Adulteration Assessment 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 Ms. Purnell via email at standra.purnell@fda.hhs.gov

Sincerely,

/s/

Jennifer Thomas
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition