U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR FOOD SAFETY & APPLIED NUTRITION

5001 Campus Drive
College Park, MD 20740

October 31, 2017

VIA EXPRESS DELIVERY

Mr. Tony Suhartono
Owner
PT. Guna Citra Kartika
Perum Bank Niago Blok C No. 12A, Ngaliyan
Semarang, Central Java 50185
Indonesia

Reference # 538201

Dear Mr. Suhartono:

On May 22 & 23, 2017, a representative of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility, PT. Guna Citra Kartika, located at Jalan Balai Desa Tambak Rejo RT.004 RW 05, Jepara, Jawa Tengah, Indonesia. That inspection revealed violations of the seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), referred to as the seafood HACCP regulation. That inspection resulted in FDA's issuance of an FDA-483, Inspectional Observations, listing the deviations found at your firm at the conclusion of the inspection. We acknowledge receipt of your response received via email on June 10, 2017, which included documentation describing corrections to the observations of concern noted on the form FDA-483, including a revised HACCP plan, a heat distribution study, and photographs of corrective actions. However, our evaluation of the documentation revealed that the response was not adequate, as further described in this letter.

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). You may find the Act, the seafood HACCP regulation and FDA's 4th Edition of the Fish and Fisheries Products Hazards & Controls Guidance (the Hazards Guide) through links in FDA's home page at www.fda.gov.

We have the following concerns:

1. You must conduct a hazard analysis 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 critical control points, to comply with 21 CFR 123.6(a) and (c) (2). A critical control point is defined in 21 CFR 123.3(b) as a "point, step, or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." However, your firm's HACCP plan for pasteurized refrigerated canned crabmeat does not list a critical control point at the (b)(4) step to control the food safety hazard of post process contamination with pathogens. Although you have a pre-requisite program, FDA requires that processing steps where a food safety hazard is prevented or be listed in a HACCP plan. Your "(b)(4)" indicates that you monitor the residual chlorine in your (b)(4) tanks; this should be included in your HACCP plan along with adequate critical limits, monitoring procedures, recordkeeping, etc., at this critical control point.

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 pasteurized refrigerated canned crabmeat lists a critical limit at the Receiving critical control point, as "(b)(4) " that is not adequate to control the food safety hazard of *Staphylococcus aureus (S. aureus).* FDA recommends that you include, in your HACCP plan, that monitoring product temperatures and adequacy of ice at receiving at this critical control point with adequate critical limits, monitoring procedures, recordkeeping, etc.

   In addition, your critical limit at the Receiving critical control point listed as "(b)(4) (b)(4) " is not adequate to control the food safety hazard of chloramphenicol contamination. FDA recommends a non-detectable critical limit for chloramphenicol. FDA further recommends that every lot be analyzed for the presence of chloramphenicol; OR every lot be accompanied by a certificate from the supplier indicating proper drug usage, i.e. no chloramphenicol used; OR inclusion of 3rd party certification of the supplier's quality assurance program; OR that firms conduct farm visits to monitor drug usage procedures and certification of proper drug usage at least once per year, along with adequate critical limits, monitoring procedures, recordkeeping, etc.

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 plan for pasteurized refrigerated canned crabmeat at the Receiving critical control point to control the food safety hazard of chloramphenicol is not appropriate. Your response indicates the corrective action: "If supplier has positive sample for chloramphenicol, the next shipments will be rejected and supplier should carried out to solve the problem. Since the crab meat free from chloramphenicol after twice testing, the supplier concerned will be allowed to deliver their crab meat." Your response is inadequate in that your revised corrective action plan does not address correcting the cause of the deviation and ensure adulterated product does not enter U.S. commerce.

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. More specifically, your response should include documentation and information that would assist us in evaluating your corrections, such as a revised HACCP plan and 5 days of completed monitoring records (full production days). If you cannot complete all corrections within 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 the Food and Drug Administration, Attention: Donald Greaves, Compliance Officer, Office of Compliance, Division of Enforcement, 5001 Campus Drive, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Donald Greaves via email at Donald.Greaves@fda.hhs.gov. Please reference CMS# 538201 on any submissions and within the subject line of any emails to us.

Sincerely,

/s/

Sabina Reilly
Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition