DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

March 10, 2015

VIA EXPRESS DELIVERY

Mr. Arjun Gadre
Managing Director
Gadre Marine Export Pvt. Ltd.
Plot No FP 1, MIDC Mirjole
Ratnagiri, Maharashtra
India 415639

Reference # 448352

Dear Mr. Gadre:

The U.S. Food and Drug Administration (FDA) inspected your seafood processing facility Gadre Marine Export Pvt. Ltd., located at Plot No FP 1, MIDC Mirjole Ratnagiri, Maharashtra, India on August 2 - 4, 2014. During that inspection, we found that you had 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, the FDA investigator issued an FDA 483, Inspectional Observations, listing the observations made at your firm.

We acknowledge receipt of your response sent via email on August 8, 2014. Your response included two revised HACCP plans and supporting documentation. One of the revised plans is entitled "Moulded Type (Unbreaded With Suwari Shreds) IQF Products" and will be referred to in this letter as the "revised HACCP plan for IQF Products". The second revised plan is entitled "HACCP Plan – Vacuum Packed Products" and will be referred to as such. Our review of the documentation your firm submitted on August 8th 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). Accordingly, your frozen imitation surimi based products (i.e., breaded and unbreaded) manufactured using a (b)(4) ((b)(4) [redacted]) 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 Fishery Products Hazards and Controls Guidance (the Hazards Guide) through links on

FDA's home page at www.fda.gov . The Hazards Guide, which provides our recommendations regarding identification and control of food safety hazards reasonably likely to occur for your fish and fishery products, can be found on our web site at: www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm .

Your significant deviations are as follows:

- Critical control points. 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 revised HACCP plan for IQF Products does not list the critical control points for cooling and maturation of the surimi (i.e., (b)(4) ingredient) to control the food safety hazard of pathogen growth, including *Clostridium botulinum* growth and toxin formation. The finished surimi products are manufactured using a series of steps before final packaging of the finished product. The steps include (b)(4) (b)(4) of the final end product. The cooling and maturation of the cooked surimi should be identified as critical control points to control *Clostridium botulinum* growth. For example, FDA recommends chilling the internal temperature of the product from 118°F(48°C) to 70°F(21.1°C) within 2 hours and to below 38°F(3.3°C) within the subsequent 4 hours. The product should then be held during maturation, as well as during any subsequent storage periods, at refrigerated temperatures of 38°F (3.3°C) or below to control *Clostridium botulinum* toxin formation.

- Critical limits. 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, we have concerns regarding both of the revised HACCP plans you submitted with your August 8th response:

  - Your firm's revised HACCP plan forIQF Products does not list critical limits at the pasteurization and labeling critical control points to prevent *Clostridium botulinum* growth and toxin formation. Specifically:

    - The critical limits listed in the plan at the "Pasteurization" critical

control point are not adequate for your "lobster tail" product (i.e., one of the products covered by this HACCP plan) because they do not appear meet the cooking requirements established in the thermal validation study for this product. The critical limits listed in the plan are "minimum length of pasteurization cycle: (b)(4) (b)(4) for minced stick" for the steaming and cooling machines (b)(4) ((b)(4)), which equates to (b)(4) minutes total time. However, the thermal validation report for the steaming and cooling machine instruction table indicates the minimum speed for the "lobster" product is 23 Hz (33 minutes minimum total time).

- There are no critical limits listed for the maximum load at the "Pasteurization" critical control point. We note that load sizes are listed per product on the thermal validation report for the steaming and cooling machine instructions. These need to be included in the HACCP plan under 21 CFR 123.6(c)(3).

- The critical limits listed at the "(b)(4) " critical control point do not specifically include assuring adequate handling instructions are used (e.g., including the declaration of "keep frozen") to control the hazard of *Clostridium botulinum* growth and toxin formation in the frozen finished product. In your August 8th response, your firm proposed to address this issue by poking holes in each bag to control the hazard of *Clostridium botulinum*. Poking a hole in the bag is inadequate because this practice does not provide a safety assurance equivalent to adequately labeling the finished product with handling instructions to "keep frozen". Moreover, poking holes in the bags will expose these packaged ready to eat products to the external environment and may result in contamination with pathogens and/or insanitary conditions. Additionally, we recommend that the labels include handling instructions to thaw the product under refrigeration (e.g., "Keep frozen, thaw under refrigeration immediately before use").

- Your firm's HACCP revised HACCP plan for Vacuum Packed Products does not list a critical limit at the "(b)(4) (Step 1)" critical control point adequate to control *Clostridium botulinum* growth and toxin formation. The plan lists that the products will be labeled "Keep Frozen"; however, we recommend that the labels include additional handling instructions to thaw the product under refrigeration (e.g., "Keep frozen, thaw under refrigeration immediately before use").

You should respond in writing within thirty (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., complete sets of monitoring records for the production of 5 production date codes of products) to demonstrate implementation of the plan, 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 seafood HACCP regulation

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 Part 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: Rosemary Sexton, Compliance Officer, Food Adulteration Assessment Branch (HFS-607), Division of Enforcement, Office of Compliance, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Rosemary Sexton via email at rosemary.sexton@fda.hhs.gov.

Sincerely,

/s/

Charlotte Christin
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition