DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740

VIA EXPRESS DELIVERY

Ms. Jill H Hechanova, Operation Manager
New Wave Exporters Inc.
Block 2 Lot 12 Gardenville Tangub
Bacolod City, Philippines

Dear Ms. Hechanova:

The U.S. Food and Drug Administration (FDA) inspected your seafood processing facility New Wave Exporters Inc located at Block 2 Lot 12 Gardenville Tangub, Bacolod City, Philippines on September 1 and 2, 2015. 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). 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 emailed response dated September 16, 2015, which included an updated HACCP plan. Your response did not address the seafood HACCP observations brought to your attention in the FDA-483. Therefore, we have continuing concerns with your fish products 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 vacuum packed smoked fish and vacuum packed dried 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 41h Edition of the Fish and Fisheries Products Hazards and Controls Guidance (the Hazards Guide) through links in FDA's home page at www.fda.gov. The 4th Edition of the Hazards Guide can be found on our web site at: http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm

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

1. You must conduct or have conducted 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)(1). 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 HACCP plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish do not list the food safety hazard of undeclared allergens.

2. 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 plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish do not list the critical control points of chilling of fish (i.e., refrigerated storage) and unrefrigerated processing for controlling the food safety hazards of scombrotoxin formation. FDA recommends that the following critical limits be established at these critical control points:

    a. The product is held at 40°F (4.4°C) or below at refrigerated (not frozen) storage critical control point.

    b. During processing (e.g., butchering, cleaning, brining, salting, smoking, drying, fermenting, pickling, mixing, fermenting, stuffing, packing, labeling, and staging) of scombrotoxin-forming fish that have not been previously frozen or heat processed sufficiently to destroy scombrotoxin-forming bacteria:

        - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 4 hours, cumulatively, if any portion of that time is at temperatures above 70°F (21.1°C);

          OR

        - The fish are not exposed to ambient temperatures above 40°F (4.4°C) for more than 8 hours, cumulatively, as long as no portion of that time is at temperatures above 70°F (21.1°C).

3. 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 plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish list critical limits at the the following critical control point that are not adequate to control the associated hazards:

    a. At the "Receiving step" critical control point, your firm's HACCP plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish list a critical limit of (b)(4) [redacted] that is not adequate, by itself, to control scombrotoxin (histamine) formation. Specifically, the critical limit does not include maximum or minimum values for sensory examination and internal

temperature measurements of fish at the time of off-loading from the harvest vessel to ensure that appropriate harvesting and onboard practices were used onboard the harvest vessel. FDA recommends that:

- For sensory examination to include a representative sample of scombrotoxin-forming fish shows decomposition (persistent and readily perceptible) in less than 2.5% of the fish in the sample with no more than 2 fish in a sample of 118 fish may show signs of decomposition.

AND

- For Internal temperature measurements:
  - For fish held iced or refrigerated (not frozen) onboard the vessel 24 or more hours after death:
    - The internal temperature should be 40°F (4.4°C) or below;

    OR
  - For fish held iced or refrigerated (not frozen) onboard the vessel from 15 to less than 24 hours after death:
    - The internal temperature should be 50°F (10°C) or below;

    OR
  - For fish held iced or refrigerated (not frozen) onboard the vessel from 12 to less than 15 hours after death:
    - The internal temperature should be 60°F (15.6°C) or below;

    OR
  - For fish held iced or refrigerated (not frozen) onboard the vessel less than 12 hours after death:
    - The internal temperature should be sufficiently below water and air temperatures to indicate that appropriate chilling methods were implemented onboard the harvest vessel. Chilling of the fish should begin on the harvest vessel regardless of the time from death until off-loading from the vessel by the processor, unless the environmental conditions (e.g. air and water temperatures) are below 40°F (4.4°C) from the time of death until off-loading from the vessel by the processor;

    OR
  - For fish held iced or refrigerated (not frozen) onboard the vessel:
    - Elapsed time from death and internal temperatures at the time of off-loading from the vessel by the processor should be consistent with cooling curves that will prevent development of an unsafe level of histamine in the specific

species, as established through a scientific study.

Furthermore, the critical limit does not include maximum or minimum values for other measurements to ensure that appropriate transportation-handling practices were used throughout transit from the fishing vessels to the plant. FDA recommends that:

- For fish delivered refrigerated (not frozen):
    - All lots received are accompanied by transportation records that show that the fish were held at or below an ambient or internal temperature of 40°F (4.4°C) throughout transit. Note that allowance for routine refrigeration defrost cycles may be necessary;

  OR

- For fish delivered under ice:
    - Fish are completely surrounded by ice at the time of delivery;

  OR

- For fish delivered under ice on an open-bed truck:
    - Fish are stored completely surrounded by ice;

      AND

    - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

  OR

- For fish delivered under chemical cooling media such as gel packs:
    - There is an adequate quantity of cooling media that remain frozen to have maintained product at an internal temperature of 40°F (4.4°C) or below throughout transit;

      AND

    - The internal temperature of the fish at the time of delivery is 40°F (4.4°C) or below;

  OR

- For fish delivered refrigerated (not frozen) with a transit time (including all time outside a controlled temperature environment) of 4 hours or less (optional control strategy):
    - Time of transit does not exceed 4 hours;

      AND

    - Internal temperature of the fish at the time of delivery does not exceed 40°F (4.4°C).

b. At the “Brining step” critical control point, your firm’s HACCP plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish list critical

limits of "Minimum (b)(4) [redacted] Minimum salt concentration of brine at (b)(4) [redacted]", and "Minimum ration of brine to fish (b)(4) [redacted]" that are not adequate, by themselves, to control *Clostridium botulinum* toxin formation. Specifically, the critical limits do not include a minimum value for brining time. FDA recommends that critical limits include the minimum or maximum values for the critical factors of the brining process established by a scientific study. The critical factors are those that are necessary to ensure that the finished hot smoked product has not less than 3.5% water phase salt and that the finished refrigerated salted dried product has not less than 5% water phase salt or a water activity below 0.97. The critical factors may include: brine strength; brine to fish ratio; brining time; brining temperature; thickness, texture, fat content, quality, and species of fish..

c. At the "Smoking of cooked fish" and "Smoking of fish" critical control points, your firm's HACCP plan for Vacuum Packed Smoked Fish lists critical limits for smoking time and temperature "Smoking (b)(4) [redacted]" that is not adequate to control *Clostridium botulinum* toxin formation. FDA recommends a critical limit of the internal temperature of the fish must be maintained at or above 145°F (62.8°C) throughout the fish for at least 30 minutes. In addition, FDA recommends that your firm monitor the internal temperature at the thickest portion of three of the largest fish in the smoking chamber using a continuous temperature-recording device (e.g., a recording thermometer) equipped with three temperature-sensing probes with continuous monitoring by the device itself, with visual check of the recorded data at least once per batch.

d. At the "Drying of brined fish" critical control point, your firm's HACCP plan for Vacuum Packed Dried Fish lists a critical limit, "Drying temperature for at (b)(4) [redacted] that is not adequate to control *Clostridium botulinum* toxin formation. Specifically, the critical limit does not include a minimum value for drying time. FDA recommends that critical limits include the minimum or maximum values for the critical factors established by a scientific study (i.e., for refrigerated (not frozen), reduced oxygen packaged products, those which must be met in order to ensure that the finished product has a water activity of less than 0.97). These will likely include drying time, input/output air temperature, humidity, and velocity, as well as flesh thickness. Other critical factors that affect the rate of drying of the product may also be established by the study.

4. 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 HACCP plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish list monitoring procedures and frequencies at the following critical control points that are not adequate to control the associated hazards:

    a. At the "Receiving step" critical control point, the monitoring procedure is not adequate to control scombrotoxin (histamine) formation. Specifically, the monitoring procedure does not ensure conformance with the critical limit of

(b)(4) [redacted] FDA recommends that your firm monitor the histamine content in the scombrotoxin-forming fish flesh by testing a minimum of 18 fish, collected representatively throughout each lot (or the entire lot when there are fewer than 18 fish in the lot). Additional fish should be examined if variability in fish-to-fish histamine content is expected to be high. Lots should consist of only one species of fish; for vessels delivering multiple species, testing should generally be done separately on each species.

b. At the "Brining step" critical control point, the monitoring procedure is not adequate to control *Clostridium botulinum* toxin formation. Specifically, the monitoring procedure for the brine to fish ratio does not address the address the weight of the fish. FDA recommends that your firm monitors other critical factors, such as the brine to fish ratio, with equipment appropriate for the measurement as often as necessary to maintain control.

c. At the "Storing in the chiller before dispatching" critical control point, the monitoring procedures is not adequate to control *Clostridium botulinum* toxin formation. FDA recommends that your firm continuously monitor the temperature of the cooler using a continuous temperature-recording device (e.g., a recording thermometer) with continuous monitoring by the device itself and a visual check of the recorded data at least once per day.

5. 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 plans for Vacuum Packed Smoked Fish and Vacuum Packed Dried Fish are not appropriate. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

   a. No product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation;

      AND

   b. The cause of the deviation is corrected.

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, 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. 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 facilities. 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 request for removal to Food and Drug Administration, Attention: Philip Bermel, Compliance Officer, Food Adulteration Assessment Branch (HFS-607), Division of Enforcement, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Mr. Bermel via email at: Philip.Bermel@fda.hhs.gov. Please reference #CMS 488101 on any submissions and within the subject line of any emails to us. You may also contact Philip Bermel via email if you have any questions about this letter.

Sincerely,

Latasha Robinson
Acting Director
Division of Enforcement
Office of Compliance
Center for Food Safety
and Applied Nutrition