DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

December 19, 2011

Mr. Constantino Rusodimos, General Manager/Owner
Pesca Fina, S.A.
Apartado 0816-01703
Panama City,
Panama

Dear Constantino Rusodimos:

On May 16 to 17, 2011, we inspected your seafood processing facility, Pesca Fina, S.A., located at Puerto Pesquero De Vacamonte, Arraijan, Panama. We found that you have serious violations of the Seafood Hazard Analysis and Critical Control Point (HACCP) Regulation, Title 21, Code of Federal Regulations, Part 123.

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 wild caught frozen tilapia packaged in reduced oxygen materials appear to be adulterated, in that the product has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it 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. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at www.fda.gov.

We acknowledge receipt of your response dated May 27, 2011 to the FDA 483 issued to your firm on May 17, 2011 however our review revealed that the response was not adequate, as further described in this letter.

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 you must have and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(a), and (b). However your firm does not have a HACCP plan for "Whole eviscerated fish, fillets, both fresh or frozen, of non-histamine producers" to control the food safety hazards of ciguatera and undeclared major food allergens. Your firm is a primary processor of fish species that pose a reasonably likely for ciguatera poisoning, Lane (Spotted Rose) Snapper, consequently your firm needs to include controls for the hazard at receipt. Without proper controls, natural

toxins from the harvest area could enter the process at unsafe levels at the receiving step. With regard to the hazard of undeclared major food allergens, FDA recommends that firms include controls in their HACCP plans to ensure all fish are labeled to accurately declare the species.

2. 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) (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 revised plan HACCP plan for "Whole, eviscerated fish, fillets both fresh or frozen of histamine producers" provided in you May 27th response does not list the food safety hazard of undeclared major food allergens. FDA recommends that firms include controls in their HACCP plans to ensure that all fish are labeled to accurately declare the species.

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 revised HACCP plan for "Whole, eviscerated fish, fillets, both fresh or frozen of histamine producers" provided in your May 27th response does not list a critical limit at the "(b)(4) " critical control point adequate to control Scombrotoxin formation. Specifically, your firm is using the (b)(4) when receiving fish directly from the (b)(4) . Your critical limits include "(b)(4) ". However, in addition to the critical limits your firm has listed, FDA recommends that your plan's critical limits include that harvest vessel records show:

   a. a critical limit specifying the time limit from time of capture to placing the fish on ice. FDA's recommendations vary dependent upon the air and water exposure temperatures and
   b. a critical limit defining cooling conditions aboard the vessel, e.g. the fish were stored completely and continuously surrounded by ice after capture.

   FDA also recommends harvest vessel records include monitoring the method of capture and where applicable the date and time of off loading/landing, and the estimated time of death and the time that fish are placed on ice after their death, the maximum exposure temperature, and the internal temperature of the fish, etc. We suggest you refer to pages 125 to 131 of the 4th Edition of the Hazards Guide for additional information related to the harvest vessel record control strategy at receiving.

4. You must implement the monitoring procedures and frequency that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b) and (c)(4). However, our

investigator noted during the inspection that from March to May 2011 your firm did follow the monitoring procedures listed in your plan for collecting vessel records for every vessel at the "Receiving fresh histamine producing fish in ice from harvest vessel" critical control point to control Scombrotoxin formation. Your response, dated May 27, 2011, indicated that vessel records were not necessary for fish harvested during the period of March to May 2011 because during this time fish were not harvested using the longline method of fishing. FDA disagrees and still considers that the same controls are necessary under all harvest conditions.

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, in your firm's HACCP plan for "Whole, eviscerated fish, fillets both fresh or frozen of histamine producers" lists corrective action plans at the:

    a. "(b)(4) " critical control point that is not adequate for the control of Scombrotoxin formation. Specifically, the "(b)(4) " corrective action listed for all (b)(4) critical limits is not adequate. The listed critical limit does not sufficiently describe what will be evaluated. FDA recommends that when (b)(4) records are inadequate or when internal temperature critical limits are exceeded, that the product be chilled until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot, **or** that the lot be rejected. When the critical limit for decomposition is exceeded, FDA recommends that the product be chilled until histamine analysis is performed on a minimum of 60 fish representatively collected from throughout the affected lot **and** to conduct a sensory examination of all fish, **or** that the lot be rejected.

    b. "(b)(4) " critical control point that are not adequate to control Scombrotoxin formation because your firm will be unable to implement the listed actions. Specifically, your actions listed as "(b)(4) " cannot be effectively accomplished because your firm's monitoring procedures require monitoring sufficient ice surrounding products (b)(4) . This method of monitoring does not provide specific temperature information and the (b)(4) monitoring frequency does not allow determining a cumulative exposure time of (b)(4) .

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

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

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, 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.

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.

Please send your reply to Food and Drug Administration, Attention: Lara Snyder, Consumer Safety Officer, Office of Compliance, Division of Enforcement, Product Adulteration Branch HFS-606, 5100 Paint Branch Parkway, College Park, MD 20740 U.S.A. If you have any questions regarding this letter, you may contact Lara Snyder via email at lara.snyder@fda.hhs.gov.

Sincerely,

/s/

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