DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
College Park, MD 20740

December 12, 2011

Mr. Jaime Maltez, President
Samuray Mar, S.A.
Apartado 6911, Zona 5
Panama City, Panama

Dear Mr. Martinez:

On July 18 to 19, 2011, we inspected your seafood processing facility, Samuray Mar, S.A., located at Calle 5a. Parque Lefevre, Edificio, Lefevre, 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 August 12, 2011 to the FDA 483 issued to your firm on July 19, 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 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 HACCP plan for non-histamine species fish, submitted with your August 12, 2011 response, does not list the food safety hazards of Undeclared Major Food Allergens and *Clostridium botulinum* toxin formation because your frozen finished products are packaged in reduced oxygen packaging (e.g., vacuum packaged).

Please refer to Chapter 19 of the 4th Edition of the Fish and Fisheries Products Hazards and Controls Guidance (i.e., the Hazards Guide) for additional information related to the hazard of undeclared allergens. FDA recommends that to control the hazard of undeclared allergens, firms include a critical control point in their HACCP plans for a label review, to ensure that the allergens, e.g., finfish are declared on each lot of labels.

Please refer to Chapter 13 of the 4th Edition of the Fish and Fisheries Products Hazards and Controls Guidance (i.e., the Hazards Guide) for additional information related to the hazard of *Clostridium botulinum* toxin formation. FDA recommends that your firm's revised HACCP plan for non-histamine species fish include a critical control point of labeling to control the hazard via labeling of the frozen product which includes a statement such as "Keep frozen" and "Important, keep frozen until used, thaw under refrigeration immediately before use".

For additional information regarding FDA's recommended controls for the hazards and controls discussed above, please refer to Chapters 13 and 19 of 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,

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

Bcc:
HFC-170 (DIOP)
HFS-605 (DE Reading File)
HFS-606 (MARCS-CMS case file # 245155)

Drafted: HFS-606: LSnyder: 11/17/2011
Science/Policy review: HFS-325: KSwajian: 12/06/2011
Concur:
HFS-607: Team Leader: MBenjamin: 12/09/2011
HFS-605: Acting Division Director: KLewis: 12/12/2011

F/T:
FEI: 3002765141
MARCS-CMS: 245155