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Food and Drug Administration

September 14, 2001

466 Fernandez Juncos Avenue  
Puerta De Tierra  
San Juan, Puerto Rico 00901-3223

WARNING LETTER  
SJN-01-18

CERTIFIED MAIL  
Return Receipt Requested

Mr. Cristobal Jimenez  
Owner/Operations Director  
Pescaderia Atlantica  
Sabana Seca Station  
Puerto Rico, 00952-5454

Dear Mr. Jimenez:

An investigator from the San Juan District Office conducted an inspection at your warehouse and distribution facility, located at Carretera 867 Km 1.5, Barrio Sabana Seca, Toa Baja, Puerto Rico, from March 5 through 8, 2001. The investigator found that you have serious deviations from the U.S. Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your scombrototoxin species, live oysters and clams and your imported products to be in violation of section 402(a)(4) of the U.S. Federal Food, Drug, and Cosmetic Act. The deficiencies found during the inspection, and reported on the List of Inspectional Observations, FDA-483, presented at the conclusion of the inspection include the following

HACCP Requirements

- You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR Parts 123.6(c)(4). However your firm's HACCP plan for live shellfish (i.e., clams and oysters) lists a monitoring procedure at the receiving critical control point that is not adequate to control pathogens, chemical contaminants and natural toxins from the harvest water. Specifically, your plan does not list that "every" container of shellfish will be monitored for the presence of the tags. As required for compliance with 123.28(c) and (d), each container or sack of shellfish must be monitored to verify that it bears the tag with the information required by 12 CFR Part 1240.60 (b)(c) and (d).
- You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR Part 123.6(b). However, your firm did not record monitoring

observations of any critical limits at any critical control points as listed in the HACCP plans for any of your products. Specifically, you did not record any of the monitoring observations listed in your HACCP plan for your histamine (scombroid forming) species at receiving and finished product storage. In addition, you did not record any of the monitoring observations listed in your HACCP plan for your live shellfish (clams and oysters) at receiving and storage.

- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR Part 123.7(b). However, corrective action plan for your histamine (scombroid) species at the finished product storage critical control point is not appropriate. Specifically, the actions of adding ice or transferring product from a damaged cooler to an alternate cooler does not ensure that product that has been temperature abused and that which may be injurious to health does not enter into commerce. According to the Hazard Guide, appropriate corrective actions for storage of histamine forming species include either destroying the product or diverting the product to non-food use or collecting and analyzing a representative sample for histamine.

In addition to the deviations cited above, we recommend that your HACCP plan for Histamine (scombroid) species specify the common or usual name of the scombroid species handled by your firm.

### Importer Requirements

- You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR Part 123.12(a)(2)(i). However, your firm does not have product specifications for frozen cold smoked vacuum packed salmon from [REDACTED] and fresh whiting from [REDACTED].
- You must fully implement an affirmative step to ensure that the fish and fishery products that you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR Part 123.12(a)(2)(ii). However, as part of the requirement for 21 CFR Part 123.12(a)(2)(ii)(D), your firm does not maintain a written guarantee from the foreign processor, to accompany the HACCP plan, for the fresh whiting from [REDACTED], the frozen salted cod from [REDACTED] and the sardines and anchovies from [REDACTED].

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, HACCP summary, monitoring records, written product specifications, letter of guarantees

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or other useful information that would assist us in evaluating your corrections. If you believe the hazards listed above are not reasonably likely to occur in your products, you must provide U.S. FDA with adequate, written documentation that clearly supports your reasoning. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on "Detention Without Physical Examination." You can find the U.S. Federal Food, Drug and Cosmetic Act and the Seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

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 regulations (21 CFR Part 123), and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the US Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, P.R. 00901-3203, Attention: Mary L. Mason, Compliance Officer.

Sincerely,



Mildred R. Barber  
San Juan District Office