



Food and Drug Administration

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

December 27, 2000

WARNING LETTER
SIN-01-05

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Antonio Valeriano
President
Peche de Puerto Rico, Inc.
P.O. Box 25682
San Juan, P.R. 00929-0682

Dear Mr. Valeriano:

On November 22, 29 & 30, 2000, the Food And Drug Administration (FDA) conducted an inspection of your seafood warehouse and distribution facility located at 683 Julio Andino St., Urb. Villa Prades, Rio Piedras, P.R. The investigator documented serious deviations from Title 21, Code of Federal Regulations, Part 123 "Fish and Fishery Products", (Seafood HACCP Regulation), causing your fishery products to be adulterated within the meaning of Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act, as follows:

1. Failure to have an adequate, written Hazard Analysis and Critical Control Point (HACCP) plan containing at a minimum, a list of food safety hazards that are likely to occur, as identified in accordance with 21 CFR 123.6 (a), and a list of the procedures and frequency that will be used to monitor each critical control point. For example, the metal particles associated with the band saw used to cut frozen fish, [21 CFR 123.6 (b)], and the control of pathogens from the harvest area. [21 CFR 123.6 (c)]
2. Failure to have sanitation control procedures to monitor the conditions and practices during processing with sufficient frequency to ensure, at a minimum, conformance with those conditions and practices specified in part 110 such as: safety of the water that comes into contact with the product; exclusion of pests from the plant; storage and use of toxic compounds; and the condition and cleanliness of food contact surfaces including the metal part of the band saw used to cut frozen fish and the packaging materials. [21 CFR 123.11 (b)]

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3. As an importer of fish and fishery products (i.e. frozen kingfish, octopus and yellow tail snapper from India, the Philippines and Brazil respectively), your firm has failed to have and implement written verification procedures as required in 21 CFR 123.12, that include product specifications in accordance with § 123.12 (a) (2) and at least one affirmative step according to § 123.12 (a) (2) (ii).
4. Failure to reassess the adequacy of the HACCP plan whenever any changes occur that could affect the hazard analysis or alter the HACCP plan in any way or at least annually. Your HACCP plan was last signed and dated on 8/20/1998. [21 CFR 123.8 (a) (1)]

We issued an untitled letter to Mr. Marlon Tomas, General Manager, dated June 1, 1998 including deviations found during a prior inspection conducted on May 20 & 26, 1998. Some of those deviations are similar to those reported during the recent inspection and no action has been taken to correct them.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify the San Juan District office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the US Food and Drug Administration, San Juan District Office, 466 Fernández Juncos Ave., San Juan, P.R. 00901-3223, Attention: Jorge L. González, CSO/Acting Compliance Officer.

Sincerely,



Wayne Matthews
Acting District Director

cc Mr. Marlon Tomas, Gen. Mgr.