



March 30, 1999

WARNING LETTER
SJN-99-07

Certified Mail
Return Receipt Requested

Mr. Start T. Wu
President
Eureka Marine Products Co.
1951 NW 22nd St.
Fort Lauderdale, FL 33311

Dear Mr. Wu:

On January 12 and 20, 1999, the Food and Drug Administration (FDA) conducted an inspection of your shrimp aquaculture farm, Eureka Marine Products Co. of Puerto Rico, located at Road # 165, Km. 22.1, Bo. Mameyal, Dorado, PR. Our Investigator documented serious deviations from Title 21 Code of Federal Regulations (21CFR) Part 123, "Safe and Sanitary Processing and Importing of Fish and Fishery Products," (Seafood HACCP Regulations), causing the shrimp to be adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug and Cosmetic Act (the Act), as follows:

1. Failure to have and implement a written HACCP plan to control critical points in the processing of shrimp [21 CFR 123.6 (b)]. Such hazards may include but are not limited to:

Control of the misuse of aquaculture drugs in shrimp at the receiving step.

2. Failure to maintain sanitation control records that document the monitoring of sanitation [21 CFR 123.11 (c)].

Monitoring of sanitation elements such as the condition, cleanliness and maintenance of hand-washing/ sanitizing facilities or food contact surfaces, prevention of product contamination and pest exclusion measures are not being recorded.

Before the conclusion of the inspection, your firm notified our investigator that the deficiency concerning the rodent excreta pellets in the warehouse had been corrected, but this was not verified during the inspection. A target date of April 1, 1999 was set for correction of the other deviations listed above.

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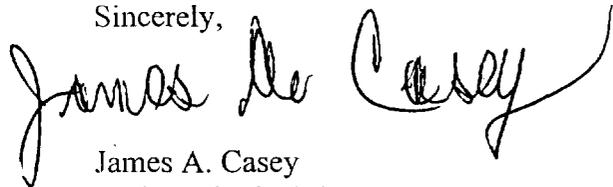
On October 13, 1998, we issued a post-inspection letter, addressed to Mr. Ahiezel González, listing deviations found during an inspection of this facility on September 16, 1998. Most of the deviations, which were listed in the post-inspectional letter, are the same as those listed in this letter. No action was taken to correct them since our last visit to your firm.

You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

Please notify this office in writing, within 15 working days of 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 similar violations. If corrective actions can not be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

Your reply should be sent to the Food & Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, PR 00901-3223, Attention: Mary L. Mason, Compliance Officer.

Sincerely,

A handwritten signature in black ink that reads "James A. Casey". The signature is written in a cursive style with a large, sweeping flourish at the end.

James A. Casey
Acting District Director

Cc: Mr. Ahiezel González, Administrator
Eureka Marine Products Co. of PR
P.O. Box 735
Dorado, PR 00646-0735