



January 6, 1999

FOOD & DRUG ADMINISTRATION  
466 FERNANDEZ JUNCOS AVENUE  
SAN JUAN, P.R. 00901-3223

**WARNING LETTER**  
SJN-99-02

**Certified Mail**  
**Return Receipt Requested**

Mr. Alan Charak  
President  
Sea World, Inc.  
1268, 30SE Street  
Caparra Terrace  
Rio Piedras, P.R. 00936

Dear Mr. Charak:

On October 20 & 22, 1998, the Food and Drug Administration (FDA) conducted an inspection of your fish importing and repacking plant located at 1268 30 SE St., Caparra Terrace, P.R. The 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 Regulation), causing the fish products 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 potential hazards of scombrototoxin formation in scombroid fish species handled by your firm (21 CFR 123.6(b)).
2. Failure to maintain sanitation control records (21 CFR 123.11(c)) that document the monitoring and corrections of sanitation conditions specified in the regulations (21 CFR 123.11(b), for example, plant water (ice) safety, condition and cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, and exclusion of pests.

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We issued you a post-inspection letter dated April 7, 1998 pointing out deviations found during a prior inspection made on February 10 & 12, 1998. Those deviations are the same as those observed during the recent inspection and no action have 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 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 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 Food and Drug Administration, San Juan District Office, 466 Fernandez Juncos Ave., San Juan, Puerto Rico 00901-3223, Attention: Andres Toro, Compliance Officer.

Sincerely yours,

  
Jeremiah D. Beckwith, Jr.  
Acting District Director

HFR-SE540:AMR:1/6/99

cc: EF  
CB(W/L)  
HFR-SE1  
HFA-224  
HFC-210  
HFI-35(REDACTED)  
HFS-636(FAX)  
DD  
DIB  
J.PARES