



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g3485d

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(781) 596-7700
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WARNING LETTER
NWE-30-02W

VIA FEDERAL EXPRESS

August 26, 2002

Adam B. Weinberg
President
Boston SeaFarms, Inc.
8 Seafood Way, Docks 39-42
Boston, MA 02110

Dear Mr. Weinberg:

We inspected your firm located at 8 Seafood Way, Docks 39-42, Boston, MA on July 30 through August 7, 2002 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your fish products, such as tuna, mahi-mahi and swordfish, to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The serious seafood HACCP deviations were as follows:

1. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at either the receiving or storage critical control points (CCP) to control the histamine hazard listed in your HACCP plan for tuna and mahi-mahi.
2. 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 123.12(a)(2)(i). However, your firm does not have product specifications for swordfish imported from Chili.
3. You must implement an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulation, to comply with 21 CFR 123.12(a)(2)(ii). However, your firm did not perform an affirmative step for swordfish manufactured by Humboldt Current Fish & Seafood, SA Puerto Montt, in Chili.

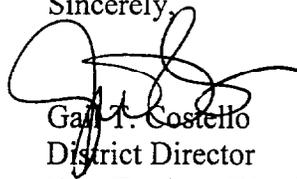
We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may also wish to include documentation such as your current monitoring records or other useful information that would assist us in evaluating your corrections. 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 deficiencies.

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 and the Good Manufacturing Practice regulations (21 CFR Part 110).

You may direct your reply to Karen N. Archdeacon, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Ms. Archdeacon at (781) 596-7707.

Sincerely,



Gary J. Costello
District Director
New England District Office