



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Public
HFI-35

SDV

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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WARNING LETTER

NWE-07-01W

VIA FEDERAL EXPRESS

January 12, 2001

Robert Iseley
President
Coastal Seafood
35 Lexington Avenue
South Norwalk, CT 06854

Dear Mr. Iseley:

We inspected your firm, located at 35 Lexington Avenue, South Norwalk, CT, on December 13 and 14, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your crabmeat products 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 deviation was as follows:

- Failure to have written product specifications for crabmeat that is imported from Ecuador, to comply with 21 CFR 123.12(a)(2)(i).

We may take further action if you do not promptly correct this above violation. 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 wish to include in your response documentation such as copies of temperature monitoring records for your cooking, cooling and storage steps 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 deviations.

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 also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

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) 279-1675, Extension 113.

Sincerely,


Gail T. Costello
District Director
New England District Office