



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

g1413d

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WARNING LETTER

NWE-26-01W

VIA FEDERAL EXPRESS

June 4, 2001

Mark S. Bulman
President
South Cape Seafood, Inc.
1084 Main Street
Chatham, MA 02633

Dear Mr. Bulman

We inspected your firm, located at 1084 Main Street, Chatham, MA, May 9 and 10, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention during a previous inspection, cause your seafood 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 deviations were as follows:

- You must implement the recordkeeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm does not record monitoring observations at the receiving critical control point (CCP) to control histamines for scromboid species received by your firm. For example, during the inspection, there were no temperatures documented to show that the fresh tuna or bluefish received at your firm were below 40°F.

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for cooked lobstermeat lists a critical limit of [REDACTED] for [REDACTED] minutes at the cooking critical control point. This may not be adequate to control pathogen growth in this ready to eat product. We do note, however, that your records indicate your cooking lobster to an internal temperature of more than [REDACTED]

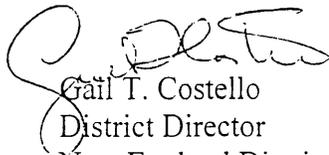
We may take further action if you do not promptly correct these above violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

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 wish to include in your response documentation such as your modified HACCP plan 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 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 1708.

Sincerely,



Gail T. Costello
District Director
New England District Office