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WARNING LETTER

NWE-18-01W

VIA FEDERAL EXPRESS

April 14, 2001

Sean Mooney
President
Specialty Foods Boston, Inc.
34 Allen Street
Somerville, MA 02143

Dear Mr. Mooney:

We inspected your firm, located at 34 Allen Street, Somerville, MA, on March 28 and 29, 2001 and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR Part 123). This deviation, which was previously brought to your attention, 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 deviation was as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). Your firm does not have a written HACCP plan for vacuum-packed smoked seafood to control the food safety hazard of *C. botulinum*. We understand you are keeping temperature records for the refrigeration unit that stores these products, however, you must have a written HACCP plan in effect at the firm.

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 this deviation. You may wish to include in your response documentation such as the written 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