



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

Surges
12/21/00

m4995n

One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675
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December 19, 2000

WARNING LETTER

NWE-04-01W

VIA FEDERAL EXPRESS

James Miller, President and CEO
U.S. Food Service, Inc.
9755 Patuxent Woods Drive
Columbia, MD 21046

Dear Mr. Miller:

On November 21, 2000, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 237 Otrabando Avenue, in Norwich, CT. The inspection revealed that you have a serious deviation from the seafood HACCP¹ regulation (21 CFR Part 123) that causes the seafood salad being processed² by your firm to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (FFD&C Act). You can find this act and the seafood HACCP regulation through links in FDA's Internet home page at www.fda.gov.

The deviation (from the HACCP regulation) 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). However, your firm does not have a HACCP plan for seafood salad to control the food safety hazard of pathogen growth and toxin formation (other than *Clostridium botulinum*) as a result of time and/or temperature abuse.

¹ Hazard Analysis Critical Control Point. HACCP entails (1) identifying food safety hazards that, in the absence of appropriate controls, are reasonably likely to occur in your products and (2) having these controls at "critical control points" during processing to eliminate or minimize the likelihood that the identified hazards will occur.

² Receipt and storage are considered processing steps under the 21 CFR Part 123.

Although you have not developed a formal HACCP plan to control the hazard associated with this product, our inspection revealed that monitoring and control procedures are being carried out with respect to the receipt and storage (critical control points) of this product. These activities must be formally incorporated into a plan.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

A copy of the Form FDA 483 (Inspectional Observations) that was issued at the conclusion of the inspection to Mr. Richard P. Gauger, President of U.S Food Service, Norwich, CT is enclosed for your reference.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct this violation. You may wish to include in your response documentation (e.g., the HACCP plan and associated 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 this deviation.

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 FFD&C Act, the seafood HACCP regulation, and the Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the FD&C Act and all applicable regulations.

Please send your reply to Mark Lookabaugh, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Fourth Floor, Stoneham, MA 02180. If you have any questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.279.1675 x1718**.

Sincerely,



Gail T. Costello
Director
New England District

Enclosure

cc: _____
Robert Tobin, President and CEO
Ahold USA
14101 Newbrook Drive
Chantilly, VA 20151