



Telephone (973) 526-6008

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

WARNING LETTER

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

September 19, 2002

**File # 02-NWJ-30**

Mr. Paul Savini  
Division President  
U.S. Foodservice Inc.  
360 South Van Brunt Street  
Englewood, New Jersey 07631

Dear Mr. Savini:

We inspected your firm, located at 360 South Van Brunt Street, Englewood, New Jersey on August 19, 20 & 26, 2002 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 Scombrotoxic species fresh fish (tuna, mackerel, mahi-mahi and bluefish) and canned, pasteurized crabmeat to be adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug & 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](http://www.fda.gov).

The deviations found were as follows:

- Your firm does not have written HACCP plans for the receipt and subsequent refrigerated storage of canned, pasteurized crabmeat and ready-to-eat seafood salads containing shrimp, tuna or surimi. In order to comply with 21 CFR 123.6(b), you must have written HACCP plans to control the potential food safety hazards of Clostridium Botulinum toxin formation, histamine production and pathogen growth for these products. Documents reviewed and collected by our investigators during the current inspection showed that you received and subsequently stored these products on at least six distinct occasions during this calendar year. Further, no monitoring records were generated to document that these lots were not subjected to temperature abuse.

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- You must fully implement the record keeping and monitoring systems identified at the receiving and storage critical control points (CCPs) in your HACCP plans for histamine-producing fish and vacuum-packaged smoked salmon, in order to comply with 21 CFR 123.6(b). However, the monitoring activities performed by your firm at this CCP are inadequate to control the food safety hazards of Clostridium Botulinum toxin formation and histamine production. Your receiving records revealed that you received shipments of these products on fifty-six distinct occasions during the months of January, May and August 2002. For forty-eight of these lots, temperature monitoring was not performed and/ or no monitoring record was generated at the time product was received. Additionally, cooler storage temperatures were either not monitored or not documented as having been monitored on May 23, 24, 27, 28 and 29; July 11, 12, 13, 14 & 25; and August 8, 2002. Your firm's lack of adequate monitoring procedures for the receipt of fish or fishery products with inherent food safety hazards was previously brought to your attention during our inspection of March 1, 2001.
- You must have HACCP plans which list monitoring procedures that are adequate to insure that the critical limits in your plans are met, in order to comply with 21 CFR 123.6(c)(4). However, your HACCP plans for histamine producing fish and for vacuum-packaged smoked salmon do not list adequate monitoring procedures at the respective receiving CCPs in your plans. The stated monitoring procedure in both plans, [REDACTED] does not provide adequate assurance that product is held at acceptable temperatures throughout the transportation process in order to adequately safeguard against the potential food safety hazards of histamine production and Clostridium Botulinum toxin formation. The necessity to verify that these products are not subjected to temperature abuse during the transportation process was previously brought to your attention in our correspondence dated May 16, 2001.

We may take further action if you do not promptly correct these 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 three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You may wish to include in your response documentation such as a revised HACCP plan, revised monitoring procedures, copies of revised monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete

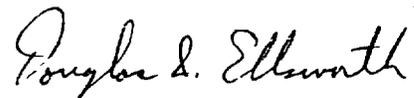
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all corrections before you respond, we expect that you will explain the reason for the delay and state when the corrections will be completed.

This letter may not list all deviations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District

CC: Scott Miller, Regional Vice President  
U.S. Foodservice Inc.  
9755 Patuxent Woods Drive  
Columbia, Maryland 21046