



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

Central Region

Telephone (973) 526-6010

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

WARNING LETTER

**Certified Mail
Return Receipt Requested**

File # 00-NWJ-12

December 9, 1999

Mr. Michael Conte
Owner/President
Conte's Pasta Co.
310 Wheat Road
Vineland, NJ 08401

Dear Mr. Conte:

During an inspection conducted by the Food and Drug Administration (FDA), on November 10, 17, 19, and 22, 1999, at your firm located at 310 Wheat Road, Vineland, NJ 08401, we documented violations of Title 21, Part 123 of the Code of Federal Regulations (21 CFR Part 123). The violations of the Fish and Fishery Product regulations cause your Conte's brand of Handmade Lobster Ravioli, Shrimp Ravioli, Lobster Ravioli, Crabmeat Ravioli, Seafood Manicotti, Seafood Stuffed Shells, Shrimp Stuffed Shells, Seafood Involtini, Salmon Ravioli, Handmade Lobster Ravioli with Spinach Pasta and Handmade Jumbo Lump Crabmeat Ravioli (raw crabmeat and precooked crabmeat), Handmade Shrimp Ravioli, Squid Ink Ravioli Stuffed with Shrimp, Handmade Lobster Ravioli with Tomato Pasta, Crabmeat Ravioli with blush sauce Microwave Meal and Lobster Ravioli with blush sauce Microwave Meal, to be in violation of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), in that your products were prepared, packed or held under insanitary conditions whereby they may have been rendered injurious to health.

The inspectional observations of concern are:

1. Your firm's Hazard Analysis Critical Control Point (HACCP) plans failed to identify and control potential hazards, specifically *Staphylococcus aureus* toxin formation and *Bacillus cereus* toxin formation for the above listed products. (21 CFR 123.6(c)(1))
2. Your firm failed to implement a seafood HACCP plan as required for the following products: Handmade Lobster Ravioli, Seafood Manicotti, Seafood Stuffed Shells, Shrimp Stuffed Shells, Seafood Involtini (with Shrimp, Lobster & Crabmeat) in Old Bay pasta, Salmon

Ravioli, Handmade Lobster Ravioli with Spinach Pasta, Handmade Jumbo Lump Crabmeat Ravioli (with Raw Crabmeat), Handmade Jumbo Lump Crabmeat Ravioli (precooked crabmeat), Handmade Shrimp Ravioli, Squid Ink Ravioli stuffed with Shrimp, Handmade Lobster Ravioli with Tomato Pasta, Crabmeat Ravioli with blush sauce Microwave Meal and Lobster Ravioli with blush sauce Microwave Meal. (21 CFR 123.6(b))

3. Your firm failed to identify the critical control points of cold storage refrigeration; thawing; cutting of seafood (e.g. crawfish, lobster, etc.); preparation of filling mix; and ravioli forming in the HACCP plans for Crabmeat Ravioli, Lobster Ravioli and Shrimp Ravioli. (21 CFR 123.6 (c)(2)(i))
4. Your firm failed to develop time and temperature controls for critical points in the processing for all of the aforementioned seafood pasta products. (21 CFR 123.6 (c)(4))
5. Your firm failed to implement the monitoring procedures listed in your HACCP plans. Specifically, your firm did not follow the monitoring procedures of checking and documenting time and temperature for the processing steps identified as critical control points to control the hazards of Staphylococcus aureus and Bacillus cereus toxin formation. (21 CFR 123.6 (c)(7))
6. Your firm failed to document actual values for monitoring data for critical control points. We observed an employee taking the temperature with a dial thermometer of the lobster ravioli filling showing a reading of 52°F but then recording the temperature as 46°F on your temperature records. (21 CFR 123.6(c)(7))
7. Evaluation of your plant sanitation found that your firm is not monitoring sanitation. Your firm is required to monitor eight different areas of sanitation as listed in 21 CFR 123.11(b), as appropriate to your plant and the food being processed.

Specific problems which must be corrected include maintaining the cleanliness of your food contact surfaces; preventing cross contamination of your products; appropriately storing your equipment, raw materials, and toxic compounds. Pasta manufacturing equipment and utensils were found used and stored not clean. Several employees were found to be wearing jewelry, which should be covered or removed while engaged in food handling. Several employees were observed to not be following appropriate sanitary food preparation and handling practices.

8. Your firm failed to calibrate equipment (e.g. thermometers, cooler, freezer) for which calibration is required as part of your verification of the controlled process. (21 CFR 123.8 (a)(2)(ii)).

A number of the objectionable conditions described above, were found in a previous inspection of your firm conducted by FDA on December 15 and 17, 1998. FDA further advised you of these conditions in a letter from this office, dated January 14, 1999. Despite these notifications, the deviations continue to occur demonstrating that your previous corrective actions have been ineffective.

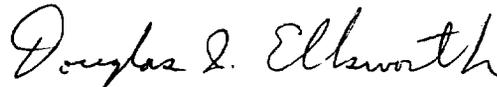
The above items are not intended to be an all-inclusive list of violations. As a manufacturer of pasta products containing seafood (e.g. lobster, crawfish, and shrimp) you are responsible for assuring that your overall operation and the food products themselves are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing within 15 working days' receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, Attention: Jill A. Mielziner, Acting Compliance Officer, at the address and telephone number above.

Sincerely yours,



Douglas I. Ellsworth
District Director