



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

93963d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
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April 15, 2003

WARNING LETTER

NWE-15-03W

FEDERAL EXPRESS

Carl L. Zuanelli, President
Nuovo Pasta Productions, Ltd.
125 Bruce Avenue
Stratford, Connecticut 06615

Dear Mr. Zuanelli:

We inspected your firm, located at 125 Bruce Avenue, Stratford, Connecticut on February 19, to 26, 2003, and found that you have a serious deviation from the Seafood HACCP regulations (21 CFR 123). This deviation causes your seafood filled pasta products to be processed by your firm 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 is 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(a) and (b). However your firm does not have a HACCP plan for any of your seafood filled pasta products to control the food safety hazards of *Clostridium botulinum* and pathogens. Your hazard analysis may determine that you may require more than one HACCP plan, and that there may be additional hazards to control.

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 §110).

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 a completed HACCP plan, or other useful information that would assist 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 deviations.

You should also review all your labels for all your products. It is your responsibility to ensure they meet FDA labeling regulations. For example, your label for the Tortellini Classic Italian Cheese net wt 10 oz. bears the incorrect place of business of the manufacturer, packer or distributor.

Further, your labels for the Classic Italian Cheese Tortellini 12 count, Crab Grilled Leek & Lemon Ravioli 90 count, Basil Linguine 10 lbs, and Porcini do not bear ingredient statements. If you have written agreements with your purchasers for these products declaring the ingredients for each product please have them on file so that we can review them on the next inspection of your facility. Otherwise, the labeling regulations require bulk containers to bear the ingredient statement. Further, because these seafood filled pasta products contain allergens they should be declared in the ingredients statement, for example, eggs, milk, wheat.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issues in this letter, please contact Mr. Ota at (781) 596-7762.

Sincerely,



Gail J. Costello
District Director
New England District