



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
New England District

g1601d

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

August 1, 2001

WARNING LETTER

NWE-35-01W

VIA FEDERAL EXPRESS

Ronald F. Nodine, President
Nodine's Smokehouse Inc.
65 Fowler Avenue
Torrington, Connecticut 06790

Dear Mr. Nodine:

We inspected your firm, located at Torrington, Connecticut, on July 2, 3, 5, and 6, 2001 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 vacuum packed fresh fish 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 deviations were as follows:

- 1) You must take an appropriate corrective action when a deviation from a critical limit occurs, to comply with 21 CFR 123.7(a). However, your firm did not take the appropriate corrective action to control *Clostridium botulinum* when your processes for hot smoked bluefish, mackerel, tuna and trout; cold smoked mussels and scallops; and cold smoked, steam cooked shrimp deviated from your critical limit at the thawing, brining or finished goods critical control points. For example, on at least four (4) occasions the temperature of your cooler was above your critical limit of [REDACTED] F for an extended period of time and there is no documentation you [REDACTED] [REDACTED] as required by your HACCP Plan.

- 2) Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for hot smoked bluefish, mackerel, tuna, and trout at the brining critical control point to control *Clostridium botulinum* is not appropriate. For example, when the critical limit has been exceeded you need to assess the product to assure the product is not injurious to health or otherwise adulterated.
- 3) You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for hot smoked bluefish, mackerel, tuna and trout; cold smoked mussels and scallops; and cold smoked, steam cooked shrimp needs to be updated to reflect that you are now using [REDACTED] instead of [REDACTED].
- 4) You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for cold smoked mussels does not list the critical control point of receiving for controlling the food safety hazard of pathogens.
- 5) You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However your HACCP plan for cold smoked, steam cooked shrimp does not list a critical limit at the steam cook critical control point to control pathogens. For example, it does not list a minimum cook time or temperature.
- 6) You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor five (5) of the eight (8) areas of conditions and practices listed in 21 CFR 123.11(b).

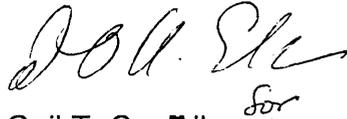
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things your are doing to correct these deviations. You may wish to include in your response documentation 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 deviations.

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). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Bruce R. Ota, Compliance Officer, U.S. Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issue in this letter, please contact Mr. Ota at (781) 279-1675.

Sincerely,

A handwritten signature in cursive script, appearing to read "Gail T. Costello".

Gail T. Costello *for*
District Director
New England District Office