



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

9/17/01

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
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WARNING LETTER

NWE- 34 -01W

VIA FEDERAL EXPRESS

August 22, 2001

Mr. Jeremiah A. Shafir, President
Kettle Cuisine, Inc.
270 Second Street
Chelsea, MA 02150

Dear Mr. Shafir:

We inspected your firm, located at 270 Second Street, Chelsea, MA 02150 July 5 - 11, 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 in letters to your firm dated October 13, 1999 and December 7, 2000, cause your cooked refrigerated seafood chowders / soups such as New England Clam Chowder to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic 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:

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 cooked refrigerated seafood chowders / soups, such as New England Clam Chowder, does not list the two critical control points, the hot fill process and refrigeration storage for controlling the food safety hazard of *Clostridium botulinum*.

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 firm's HACCP plan for cooked refrigerated seafood chowders / soups, such as New England Clam Chowder, lists a critical limit of cooking at 180 degrees F for a time of 10 minutes at the cooking critical control point that is not adequate to control *Clostridium botulinum*.

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 cooked seafood

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chowders / soups, such as New England Clam Chowder, lists a monitoring procedure at the cooking critical control point that is not adequate to control *Clostridium botulinum*. For example, your firm is not taking the temperature of the soup AFTER the refrigerated seafood is added. Once you finalize your cooking critical limit, you will need to measure it properly for each batch.

We acknowledge your letter dated July 10, 2001. We have reviewed your letter along with the supporting documents. We disagree with your position that your firm is currently controlling the *Clostridium botulinum* hazard. As stated above, and as we had informed you in a previous letter (dated December 7, 2000), you need to modify your HACCP plan to adequately control this significant hazard and to comply with the regulations. In conjunction with our previous letter, you should refer to the Fish and Fisheries Hazards & Controls Guidance, Third Edition, June 2001, particularly Chapter 13.

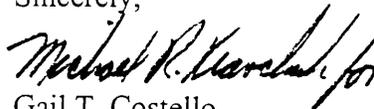
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from the 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 copies of forms and monitoring records of 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 (21CFR Part 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.

You may direct your reply to Richard B. Midwood, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Midwood at (781) 279-1675 extension 1730.

Sincerely,



Gail T. Costello
District Director
New England District Office