



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
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December 22, 2003

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-13

Kathleen A. Horner, President
Stockpot Incorporated
22505 State Route 9
Woodinville, Washington 98072

WARNING LETTER

Dear Ms. Horner:

On September 5, 2003, we inspected your firm located at 22505 State Route 9, Woodinville, Washington. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. 342 (a)(4). Accordingly, your refrigerated ready-to-use concentrated clam chowder in a reduced oxygen pouch is adulterated, in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find this Act, the seafood HACCP regulation, and FDA's Fish and Fisheries Products Hazards and Controls Guidance: Third Edition through links in FDA's homepage at www.fda.gov.

The deviations were as follows:

1. You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the critical control points, to comply with 21 CFR 123.6(a) and (c)(2). A critical control point is defined in 21 CFR Part 123.3(b) as "a point, step or procedure in a food process at which control can be applied and a food safety hazard can as a result be prevented, eliminated, or reduced to acceptable levels." Your firm's HACCP plan does not list the critical control point of container sealing for controlling the food safety hazard of *Clostridium botulinum* for your refrigerated

ready-to-use concentrated clam chowder packed in reduced oxygen pouches. Your response letter dated October 8, 2003, states that you intend to begin performing destructive seal examinations, and will add this as a critical control point in your HACCP plan. For more information on container sealing, please refer to Chapter 18 of FDA's Fish and Fisheries Products Hazards and Controls Guidance.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR Part 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard."
 - a) However, your firm's HACCP plan for your refrigerated ready-to-use concentrated clam chowder lists inadequate critical limits at the hot filling critical control point for control of the hazard of *Clostridium botulinum* in a refrigerated pouch. In your letter dated October 8, 2003, you state that you intend to include the addition of a hot filling critical control point to your HACCP plan for clam chowder for prevention of recontamination after cooking. In this letter you also correctly identify *Clostridium botulinum* as a target organism. However, the critical limit listed at this hot filling critical control point is not adequate for controlling potential recontamination by *Clostridium botulinum*. Your new hot-filling critical control point lists the critical limit temperature as greater than or equal to [REDACTED]°F. However, FDA recommends a fill temperature of 185°F for control of *Clostridium botulinum* growth and toxin formation. In addition, your processing method, described as [REDACTED] allows time for the soup to cool and increases the chance of recontamination with *Clostridium botulinum* from the air, filling tank, and pouches. FDA recommends that cooked, hot-filled soups/sauces be filled in a continuous manner directly from the cook kettle using sanitary, automated filling systems designed to minimize the risk of recontamination, while maintaining product temperature.
 - b) Your firm's HACCP plan for your refrigerated ready-to-use concentrated clam chowder lists critical limits of [REDACTED] hours to cool the product to an internal temperature of 40°F at the bag cooling critical control point, which is not adequate to control *Clostridium botulinum* growth and toxin formation. FDA recommends that product be initially cooled from 140°F to below 70°F within two hours and to a 40°F or below within another four hours.
 - c) Your firm's HACCP plan for your refrigerated ready-to-use concentrated clam chowder does not list a residual chlorine critical limit at the bag cooling critical control point. In your response letter dated October 8, 2003, you state that post pasteurization contamination from your cooling water is not likely because you are using chlorinated municipal water. You also indicate in your response that you monitor residual chlorine [REDACTED] times daily. Because chlorine levels may

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dissipate over time in your re-circulating system, FDA recommends that you include a critical limit for residual chlorine in the bag cooling critical control point in your HACCP plan to ensure that residual chlorine consistently remains at measurable levels.

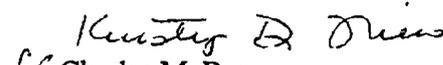
For additional information on the hazards associated with pathogens, *Clostridium botulinum* growth and toxin formation, cooking, pasteurization, post pasteurization handling practices and how these relate to developing and implementing your HACCP program, please refer to Chapters 12, 13, 16, 17 and 18 in FDA's Fish and Fisheries Products Hazards and Controls Guidance.

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 15 working days from your receipt of this letter. You may wish to include in your response documentation such as your revised HACCP plan, and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect 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 regulation and the Good Manufacturing Practice regulation (21 CFR 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.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Ms. Elrand at (425) 483-4913.

Sincerely,


for Charles M. Breen
District Director

Enclosures:

Form FDA 483

cc: WSDA with disclosure statement