



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

Telephone (973) 526-6008

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

**WARNING LETTER**

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

September 25, 2003

**File # 03-NWJ-07**

Mr. Steven Nage  
Chief Executive Officer  
America's Soup Company, Inc.  
9360 North Crescent Blvd.  
Pennsauken, New Jersey 08110

Dear Mr. Nage:

We inspected your firm, located at 9360 North Crescent Blvd., Pennsauken, New Jersey, on August 6 and 19, 2003 and found that you have serious deviations from Title 21, Code of Federal Regulations, Part 123 - Fish and Fishery Products (Seafood HACCP regulations). In accordance with 21 CFR 123.6(g), the 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 Part 123, renders that processor's fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) (codified at 21 U.S.C. § 342(a)(4)). Accordingly, the deviations noted at the inspection cause your ready-to-eat (RTE) soups that contain seafood ingredients to be adulterated within the meaning of section 402(a)(4) of the Act, in that they were prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. Some of these same deviations were also noted and brought to your attention at a previous inspection on July 3 and 8, 2002.

You can find the Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>. The third edition of the Fish and Fisheries Products Hazards and Controls Guidance, which we also recommend that you use as a reference, can also be found on-line at <http://www.cfsan.fda.gov/~comm/haccp4.html>.

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During our inspection, the investigators provided you with the Form FDA 483 which presents their evaluation of your firm's performance regarding various aspects of the HACCP requirements. Upon further review, we found the following serious deviations from the principles of HACCP and the significant requirements of the program:

- You must conduct a hazard analysis in order to determine if there are food safety hazards that are reasonably likely to occur and develop and implement a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6 (b). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical or physical property that may cause a food to be unsafe for human consumption." However, your firm does not have a written HACCP plan for the manufacture and subsequent refrigerated storage of RTE seafood products, including New England Clam Chowder, Manhattan Clam Chowder, Maryland Crab and Seafood Combination soups. You must have and implement a written HACCP plan to control the potential food safety hazards of Clostridium Botulinum and Staphylococcus Aureus toxin formation and pathogen growth (Bacillus Cereus and Salmonella) for these products. Your lack of written HACCP plan(s) to control the potential food safety hazards inherent in your seafood products was previously brought to your attention during our inspection on July 3 and 8, 2002.
- You must adequately monitor sanitation conditions and practices at your firm during processing and take appropriate corrective actions when warranted, in order to comply with 21 CFR 123.11(b). However, your firm did not perform sanitation monitoring with sufficient frequency to assure control. For example, our investigators observed sanitation deficiencies at the following key sanitation control points: (a) prevention of cross contamination (an employee was observed cutting and handling raw chicken and subsequently handling finished product without first washing and sanitizing his hands; finished soup products and raw ingredients (including raw hamburger meat) were stored directly on the floor of the walk-in refrigerator.), (b) maintenance of hand washing and toilet facilities (no hot water was available in the employee bathroom.), (c) condition and cleanliness of food contact surfaces (food preparation surfaces were observed to be cracked and contained embedded food particulate matter), (d) storage of toxic compounds and potential adulterants (insecticides were stored adjacent to canned goods; paint, building materials, debris and other extraneous items were haphazardly stored in a pile adjacent to the processing area.), and; (e) exclusion of pests (dried mouse droppings were observed in the storage area; exterior doors had gaps and were not tight-fitting, allowing for the potential ingress of vermin.)

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Your firm's lack of adequate sanitation monitoring was previously brought to your attention during our inspection on July 3 and 8, 2002.

- In order to comply with 21 CFR 123.10, you must have an individual who has successfully completed appropriate HACCP training or who is otherwise qualified through job experience develop your HACCP plan and perform the record reviews required by 21 CFR 123.8 (a)(3). Your firm does not employ or otherwise engage an appropriately trained individual to perform these functions.

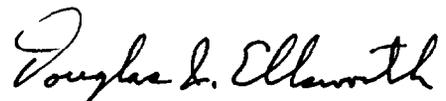
Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product(s) and/ or enjoin your firm from operating.

Please respond in writing within 15 working days from your receipt of this letter. 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 HACCP plans, monitoring procedures you have implemented, copies of 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 that you will explain the reason for the delay and state when the corrections will be completed.

This letter may not list all 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 Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Your response to this letter should be directed to the U.S. Food and Drug Administration, Attention: Richard D. Manney, Compliance Officer at the address and telephone number listed above. If you have questions regarding any issue in this letter, please contact Mr. Manney directly.

Sincerely,



Douglas I. Ellsworth  
District Director  
New Jersey District