



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

03-DAL-WL-09

Dallas District  
4040 North Central Expressway  
Dallas, Texas 75204-3145

May 1, 2003

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Mr. Victor Hsu, President  
Amy Foods, Inc.  
3324 South Richey Street  
Houston, Texas 77017

Dear Mr. Hsu:

We inspected your firm at the above address on March 3, 5, 20, and 21, 2003, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). The deviations cause your ready to eat shrimp egg rolls to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). 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 your seafood products adulterated in that the products have been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You can find the Act, the seafood HACCP regulations, and the Fish and Fisheries Products Hazards and Control Guidance, Third Edition, June 2001, through links in the FDA's homepage at <http://www.fda.gov>.

The deviations are as follows:

1. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are likely to occur, and you must have a HACCP plan to control any food safety hazards that are likely to occur, to comply with 21 CFR 123.6(a) and

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(b). A food safety hazard is defined in 21 CFR Part 123.3(f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for fully cooked, vacuum packed shrimp egg rolls does not list the food safety hazards of pathogen survival through cooking, pathogen growth through time and temperature abuse and *Clostridium botulinum* toxin formation or metal fragments attributed to manufacturing machinery at the appropriate critical control points.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met, in order to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 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." However, your firm's HACCP plan for shrimp egg rolls does not list a critical limit related to time in the [REDACTED] at the "Internal Product Temperature" critical control point to control *Listeria monocytogenes* and other pathogens.
3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor sanitation conditions and practices during processing with sufficient frequency to ensure conformance with 21 CFR Part 110, as evidenced by the use of standing room air fans used to cool ready to eat products; and the hand washing sink in the [REDACTED] [REDACTED] did not have hot water when tested by our Investigator.
4. You must provide all mandatory records for official review and copying at reasonable times, to comply with 21 CFR 123.9(c). However, a representative at your firm, Mr. Jesse Dominguez, refused to provide the HACCP plan or any documentation or any documents in the HACCP notebooks for shrimp egg rolls, for photocopying. Instead, our Investigator hand copied the records in order to conduct her review.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your egg roll manufacturing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable regulations.

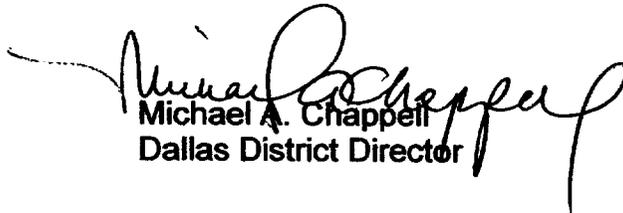
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We may take further action if you do not promptly correct these violations. For instance, we may seize your aforementioned products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific steps you are taking to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised sanitation monitoring forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Reynaldo R. Rodriguez, Jr., Director, Compliance Branch, at the above letterhead address. If you should have questions regarding any issue in this letter, please contact Mr. Rodriguez at (214) 253-5215.

Sincerely,

  
Michael A. Chappell  
Dallas District Director

MAC:rrr