



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER CIN-WL-01-7677

July 5, 2001

Cathy L. Herold
President
Herolds Salads, Inc.
17512 Miles Road
Cleveland, Ohio 44128

Dear Ms. Herold

We inspected your firm located at 17512 Miles Road, Cleveland, Ohio 44452 on April 4 through 26, 2001. Our inspection found serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) Regulations (21 CFR Part 123) and deviations from the Good Manufacturing Practice Regulations (21 CFR Part 110). These deviations, some of which were previously brought to your attention, cause your seafood and other salads and dips 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 are as follows:

1. 21 CFR Part 123.6 (b) requires a HACCP plan be implemented for all seafood products when a hazard analysis reveals that there are one or more hazards that are reasonably likely to occur. Your firm has failed to implement a HACCP plan to control the hazard of food additives particularly sulfites in your shrimp containing products. Sulfites are listed on the label of the frozen shrimp used in a number of your products. We understand that your labels for shrimp containing products do list sulfites; however, you must also have a HACCP plan in place to assure that all shrimp containing products manufactured by your facility declare sulfites.
2. 21 CFR Part 123.6 (c) requires that critical control points (CCP), critical control limits (CCL), and monitoring procedures be listed in the HACCP plan. Your HACCP plan for seafood salads does not list CCPs, CCLs, and monitoring procedures for thawing of frozen seafood ingredients and finished product storage. Moreover, our investigator observed frozen vacuum packaged surimi being thawed at ambient temperature in your processing room. This is a significant observation since the outgrowth of *Clostridium botulinum* can occur in vacuum packaged seafood products that are temperature abused.

Our inspection also found that you are not calibrating the thermometer used to monitor temperatures at the processing and packaging CCPs.

3. 21 CFR Part 123.11 requires that you monitor sanitation conditions and practices during processing, document the monitoring, take corrective actions as needed, and document those corrective actions. Your sanitation and sanitation monitoring practices are inadequate as evidenced by:
- Live and dead rodents were observed in food storage areas. One live rodent was found in a box of pasta and a dead rodent was observed in a tin mouse trap stored on top of food items;
 - Evidence of rodent activity was noted in the food processing area and raw material storage area. Rodent excreta pellets were observed on storage racks in the food processing area; rodent excreta pellets too numerous to count were found in the raw materials storage area; and at least 12 bags of pasta appeared to have been rodent gnawed.
 - Your sanitation monitoring records failed to note rodent activity for the days and weeks prior to this inspection.
 - The finding of a live rodent and exterminators visit on 4/4/01 was not documented on your sanitation monitoring records.
 - Your firm is not monitoring all 8 sanitation elements as required per 21 CFR 123.11. Safety of water, protection of food from adulterants, and prevention of cross contamination are not documented. Paper towels were not available at the hand-washing station.
 - Cooked potatoes for potato salad were observed cooling at room temperature using a fan that was positioned in front of the storage racks where the rodent excreta pellets and other rodent evidence was found.
 - An employee was observed hosing down the floor under the table while the potatoes were cooling and in the storage area when packaging was taking place.

The seal on the back door had holes. This is a potential entry point for rodents and other pests. The trash and debris around the building could harbor rodents and other pests.

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 three weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. Your response should also include documentation of your corrections, such as a copy of your revised HACCP plan for seafood salads containing CCPs, CCLs, and monitoring procedures for the seafood ingredient thawing and finished product storage steps or other useful information that would assist us in evaluating your corrections. If you can not complete all corrections before you respond, we expect that you to explain the reason for your delay and state when you will correct any remaining deviations.

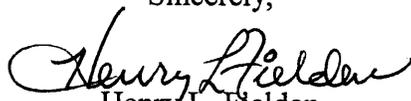
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulations (21 CFR Part 123), and the Good Manufacturing regulations (21 CFR Part 110). You also have a responsibility to use 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: Deborah Grelle, Director of Compliance, 6751 Steger Drive, Cincinnati, Ohio 45237-3097.

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If you have any questions regarding the seafood HACCP regulations, please contact FDA Investigator Kathryn McCarty at (330) 273-1038.

Sincerely,

A handwritten signature in cursive script that reads "Henry L. Fielden".

Henry L. Fielden
District Director,
Cincinnati District