



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HF-35

M 20901

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
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June 8, 1999

WARNING LETTER
CIN-WL-99-224

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Cathy L. Herold, President
Herold's Salads, Inc.
17512 Miles Avenue
Cleveland, Ohio 44128

Dear Ms. Herold:

On March 3, 8, 9, 12 and April 5, 1999 the Food and Drug Administration (FDA) conducted an inspection of your plant located in Cleveland, Ohio. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practices requirements for foods (21 CFR 110).

During the inspection the FDA investigator observed shortcomings in your system that are deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 which presents the investigator's evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. Your firm is in violation of 21 CFR 123 and 110 causing your products to be deemed adulterated under the provisions of 21 USC 342(a)(4). Because of the following:

"Failure to have and implement a written HACCP plan for Shrimp and Crab Salad to address food safety hazards such as pathogen growth and food additives (sulfites) that are reasonably likely to occur (21 CFR 123.6(b))."

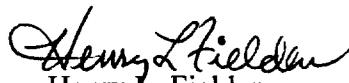
"Failure to maintain sanitation control records that as a minimum document the monitoring and corrections prescribed in 21 CFR 123.11(b) and 123.11(c)."

It is essential that you respond to this office on this matter within 15 working days of the receipt of this letter. If corrections are not made FDA may initiate regulatory action such as civil seizure or injunction without further notice.

Your reply relating to these concerns should be directed to the FDA, Attention: Leonard J. Farr, Compliance Officer. If you have any questions regarding the implementation of the HACCP regulations, or the application of HACCP to your specific process, you may contact Mr. Farr at 513-679-2700 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP system in your plant.

Sincerely,


Henry L. Fielden
District Director
Cincinnati District Office