

DEPARTMENT OF HEALTH AND HUMAN SERVICES



**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-99-25

January 8, 1999

Ronnie Cruse, Co-Owner
Medart Seafood
US 98 & 319
P.O. Box 445
Panacea, FL 32356

Dear Mr. Cruse:

On November 3, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at US 98 & 319, Panacea, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the crabmeat processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act), as follows:

Failure to have and implement a written HACCP plan to control the potential pathogen survival through cooking and pathogen growth hazards that are reasonably likely to occur with the cooked crabmeat processed and distributed by your facility. [21 CFR 123.6(b)]

Your cooler thermometer is not calibrated, i.e. it read 39° F, compared to a calibrated thermometer which read 48° F. [21 CFR 123.8(a)(2)(ii)]

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is written in a cursive style with a large, looping initial "D".

Douglas D. Tolen
Director
Florida District