



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-72

September 11, 1998

James E. Griffin, President
Cracker Seafood, Inc.
2609 22nd Causeway
Tampa, FL 33619

Dear Mr. Griffin:

On July 28, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 2609 22nd Causeway, Tampa, FL. The investigator documented violations of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act) and Title 21, Code of Federal Regulations (21CFR), Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products," (Seafood HACCP Regulation), as follows:

Failure to have and implement a written HACCP plan for the shrimp repacked by your firm to control the food safety hazard of sulfites that is reasonably likely to occur [21 CFR 123.6(b)].

Failure to maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and corrections of sanitation conditions specified in the regulations [21 CFR 123.11(b)], for example, plant water (ice) safety, condition and cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, and exclusion of pests.

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

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.

M2000N HFI-35 WJ 9/18/98

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 or injunction.

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. 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. Also include copies of any available documentation demonstrating that corrections have been made.

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