



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
Atlanta District Office

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60 8th Street, N.E.  
Atlanta, Georgia 30309

October 7, 1999

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

Grady G. Davis, Owner  
G. H. Davis & Sons  
P.O. Box 37  
Davis, NC 28524

**Warning Letter**  
00-ATL-01

Dear Mr. Davis:

On June 28 & 29, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at Horseshoe Road, Davis, North Carolina. The investigator documented deviations from FDA's seafood processing regulations. Based on the FDA inspections, shrimp produced by your firm is adulterated under Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act) in that your firm did not operate in accordance with the requirements of Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations are as follows:

1. Your firm has not met the requirements of 21 CFR 123.6(b) to have a HACCP plan for the hazard of undeclared sulfites in shrimp, a hazard which is reasonably likely to occur.
2. Your firm has not met the requirements of 21 CFR 123.11 to monitor sanitary conditions and maintain sanitation control records that document monitoring and corrections. Our investigator documented several instances resulting from this failure including conditions in general disrepair, a dog in the processing room, and the absence of hand-washing or toilet facilities.

We are obviously very concerned about these findings. The above deviations were previously brought to your attention on our letter dated August 24, 1998, to which, according to our records, you never responded.

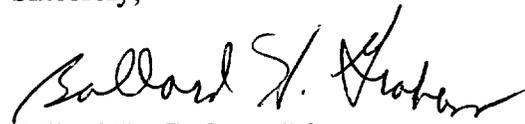
The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

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

We request that you 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 the recurrence of similar violations. If corrective action 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 Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309.

Sincerely,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is written in a cursive style with a large initial "B".

Ballard H. Graham, Director  
Atlanta District