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HFI-35

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

m22711



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

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

FLA-99-14

November 20, 1998

Clarence H. Murray, President
B & E Seafood Co., Inc.
6902 N. 21st St.
Tampa, FL 33610

Dear Mr. Murray:

On September 24, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 6902 N. 21st Street, Tampa, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products 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 properly identify in the HACCP plan or control all of the hazards that are reasonably likely to occur in the production of breaded shrimp, i.e. metal particles from processing equipment including the metal conveyor belt. [21 CFR 123.6 (b) & (c)]

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

In addition, there is no record of the review of monitoring records required in your HACCP plan to ensure completeness and verify that critical limits are followed and there are no calibration records for the thermometers used to monitor batter and storage temperatures. [21 CFR 123.8(a)(3)]

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,



Douglas D. Tolen
Director
Florida District