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Certified/Return Receipt Requested

April 15, 1999

Food and Drug Administration  
Kansas City District Office  
11630 West 80th Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

John Dirk Dickerson, Owner  
Fish And More  
2917 Brooklyn  
Kansas City, MO 64109

KAN #99-017

Dear Mr. Dickerson:

An inspection of your firm on February 2 to 5, 1999, by Food and Drug Administration Investigators from this office, and an Inspector with the Missouri Department of Health, revealed fresh buffalo fish and catfish are processed at, and distributed from, your facility under serious deviations from Title 21, Code of Federal Regulations (21 CFR), Part 123. These deviations cause these products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act).

As we explained in a previous letter to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) **identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products;** and (2) **having controls at Acritical control points@ in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of fresh buffalo fish and catfish deviates from the regulations contained 21 CFR Part 123 as follows:

- Failure to have and implement a written HACCP plan to address potential hazards associated with the seafood products processed in accordance with 21 CFR 123.6.
- Failure to maintain sanitation monitoring and control records for all days of production [21 CFR 123.11(c)], as evidenced by:

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- unshielded lights in the freezer area, directly over uncovered seafood;
- food products are being improperly stored to protect against contamination and/or deterioration;
- unsanitary conditions noted include a water hose used for hand washing and clean-up stored on the floor; a shovel used for ice, on the floor; debris and rust inside the ice maker; excessive build-up fish matter and rust on the processing table, walls and weigh scales; and excessive debris within the facility.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA 483 which is a list of the investigators' observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

  
W. Michael Rogers  
District Director  
Kansas City District