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Food and Drug Administration
New Orleans District
Southeast Region
6600 Plaza Drive, Suite 400
New Orleans, Louisiana 70127

Telephone: 504-253-4519
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April 10, 2002

WARNING LETTER NO. 2002-NOL-26

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Alexander S. Mijalis, President
Farmers Seafood Company, Inc.
1192 Hawn Avenue
Shreveport, Louisiana 71107

Dear Mr. Mijalis:

We inspected your firm, Farmers Seafood Company, Inc., located at 1192 Hawn Avenue, Shreveport, Louisiana, on November 5 – 8, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Parts 123 (21 CFR 123) and the Current Good Manufacturing Practice regulations, 21 CFR 110. These deviations cause your fresh and frozen seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed, or held under conditions whereby they may become contaminated with filth or whereby they may be rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for repacked IQF shrimp to prevent the food safety hazard of undeclared sulfiting agents. Our investigator found a package of IQF shrimp that declared sulfites. However, Mr. John Mijalis indicated in a conversation with our investigator that he did not know if the shrimp contained sulfites. This suggests that, at a minimum, you need receipt and labeling critical control points in your HACCP plan to prevent the hazard of undeclared sulfites in shrimp.
- You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take corrective actions to control pathogen growth and toxin formation when:
 - 1) Our investigators observed that for three days there was no ice surrounding your ready-to-eat seafood in your cooler to control pathogen growth and toxin formation; and,

- 2) Ready-to-eat seafood products were received routinely without ice or cooler packs surrounding the product.
- The inspectors noted that your firm is monitoring cooler temperature at the storage critical control points for all of your products. However, your firm's HACCP plan lists monitoring the presence of ice as the critical limit at the storage critical control point in all of your HACCP plans. Your HACCP plans should reflect the steps you are actually taking. If you choose to list cooler temperature instead of adequacy of ice, you must keep adequate records of the monitoring activity and take appropriate corrective actions if monitoring reveals that a critical limit has been compromised. The cooler temperature should be monitored on a continuous basis. Continuous temperature monitoring requires the installation of a temperature-recording device to provide monitoring records of the cooler temperatures during non-business hours, holidays and weekends.

In addition to the HACCP deviations, the investigators documented insanitary conditions associated with the construction and design of your facility and processing equipment. For example:

- Loading dock doors leading into the processing facility from the outside did not close completely, allowing flies to enter the plant's processing areas from outdoors;
- A sewer line, located near a loading dock on the south side of the plant, discharged raw sewage which is a potential reservoir of pathogens and attracted numerous flies;
- Plastic curtains contacted the floor and ice used on processed fish during packing. The curtains were not washed or sanitized; and,
- Wooden-handled knives were used for processing fish.

You have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. Failure to exclude flying pests is a potential contributing factor to microbiological contamination in that:

- Numerous flies were observed on and around greenish-black, foul smelling water that had backed up from the sewer line next to the south loading dock door of the facility;
- Flies were observed flying into the plant from under the south loading dock door and within the plant;
- Numerous flies were observed throughout the processing area landing on ceilings, walls, and cutting boards;
- Flies were observed landing on cutting boards that were not washed or sanitized and were then used to process fish; and,

- Ants were observed crawling in and out of the south loading dock area through a gap underneath the west dock door.

Food processing equipment is not maintained in a sanitary condition to prevent food from becoming adulterated. For example:

- Two cutting boards used to process fish were gouged and brownish residues were embedded in the crevices; and,
- The metal rings of a fish scaler used to process fish were rusted and contained residues from previous operations.

The investigators found that employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of those items from microorganisms or foreign substances. For example:

- An employee used a rubber squeegee on the fish processing table that previously rested on the wet floor. The table was not washed or sanitized before processing fish; and,
- An employee wore a wristwatch and had a bandage on his finger while processing fish.

Utensils and equipment are not cleaned and sanitized in a manner that protects food and food contact surfaces from contamination. For example, your firm does not sanitize processing equipment and utensils after washing.

You have failed to keep the grounds about your processing facility in a condition that will protect against contamination of your products. For example:

- Pieces of food, discarded food wrappers, and trash were observed behind equipment in the southwest corner of the south loading dock area. Four live, house-type flies were on the wall above the area; and,
- Dead flies, dried fish fins, fish scales, and an open plastic container with food residues were observed on a rusty table in the large fish cutting room.

We may take further action if you do not promptly correct these violations. For instance, we may seize your products and/or enjoin your firm from operating.

We are aware that at the close of the inspection, on November 8, 2001, you made a verbal commitment to correct observed deficiencies. Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plans, sanitation records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483