



August 23, 2001

**WARNING LETTER NO. 2001-NOL-45**

**FEDERAL EXPRESS**  
**OVERNIGHT DELIVERY**

Mr. Tony L. Roughton, President  
Antique Mall Ltd.  
36 Sunflower Road  
Indianola, Mississippi 38751

Dear Mr. Roughton:

We inspected your firm, located at 36 Sunflower Road, Indianola, Mississippi, on June 12 and 14, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your vacuum-packed Smoked Peppered Catfish Fillets, Smoked Catfish Paté, and Catfish with Capers mousse to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

- 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 a corrective action to control *Clostridium botulinum* for samples of your hot, smoked catfish, tested by Juan L. Silva, Ph.D., Department of Food Science and Technology, Mississippi State University, on September 14, 1999, October 10, 1999, and November 10, 1999, that revealed water phase salt content results of [REDACTED]%, [REDACTED]%, and [REDACTED]% respectively. These products do not meet the minimum [REDACTED]% water phase salt content required for hot, smoked, non-vacuum-packed fish.
- 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 vacuum-packed Hot Smoked Peppered Catfish Fillets to control the food safety hazard *Clostridium botulinum* toxin formation in the finished product.

- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for Catfish Paté and Catfish with Capers does not list the critical control point of thawing frozen catfish for controlling the food safety hazard of pathogen growth and toxin formation. In addition, the same plan does not list the critical control point of refrigerating the smoked catfish after smoking operations for controlling the food safety hazard of *Clostridium botulinum* toxin formation in the finished product.
- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for Catfish Paté and Catfish with Capers does not list the following critical limits to control the hazard of *Clostridium botulinum* toxin formation in the finished product:
  - Internal temperature of the catfish prior to smoking/vent drying;
  - Brine solution concentration at the brining critical control point;
  - Minimum ratio of brine to fish at the brining critical control point; and,
  - Soak time in brine solution.
- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm failed to monitor the following as listed in your HACCP plan for Catfish Paté and Catfish with Capers:
  - Weight of the fish at the brining critical control point;
  - Time between the end of smoking and the placement of the product under refrigeration at the cooling critical control point; and,
  - Time and temperature during the paté mixing critical control point.
- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). However, your firm does not verify the water phase salt content for Catfish Paté and Catfish with Capers at the brining critical control point to control *Clostridium botulinum*.
- You must implement the verification procedure listed in your HACCP plan to comply with 21 CFR 123.8(a)(2). However, your firm has not determined the water phase salt content of your hot, smoked catfish at the smoking/vent drying critical control point since October 20, 2000, required by your HACCP plan for Catfish Paté and Catfish with Capers.

In addition, we are currently evaluating the labels for Smoked Peppered Catfish Fillet and Smoked Catfish Pate. Upon our preliminary review, the Smoked Peppered Catfish Fillet label does not contain a net weight statement or a nutritional statement. The Smoked Peppered Catfish Fillet label suggests that the product be kept frozen or refrigerated. Please note that the *Fish and Fishery Products Hazards and Control Guide* states that products packaged under vacuum must be kept frozen to avoid the formation of *Clostridium botulinum* toxin. Our review of your Smoked Catfish Pate label packaged in the 3.5-lb. container size reveals it does not contain a dual net weight statement, a complete list of ingredients, and a nutritional statement.

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

Supervisor, promised to make some corrections and bring these deviations to your attention. 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 copies of your HACCP plans, processing, and temperature monitoring 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 Good Manufacturing Practice regulations (21 CFR 110). 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