



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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July 11, 2001

**WARNING LETTER NO. 2001-NOL-36**

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

Mr. Roger D. McCann, Owner  
McCann's Seafood  
4215 Highway 28 East  
Pineville, Louisiana 71360

Dear McCann:

We inspected your firm, located at 4215 Highway 28 East, Pineville, Louisiana on June 22, 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 oysters and fresh pasteurized crabmeat 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 following deficiencies were documented during the inspection:

- Your firm has not conducted a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for your oyster and crabmeat products to comply with 21 CFR 123.6(a).
- 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 shucked and shellstock oysters to control the food safety hazards of pathogens, natural toxins, and chemicals from the harvest areas. In addition, your firm does not have a HACCP plan for fresh pasteurized crabmeat to control the food safety hazards of pathogen growth and toxin formation. Note that this was previously brought to your attention in our letter to you dated June 1, 1999.
- You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the protection of food from adulteration with contaminants as evidenced by a soiled piece of cardboard resting directly on cooked crawfish in the cooler. Note that this was previously brought to your attention in our letter to you dated June 1, 1999.

- You failed to maintain records documenting the following information upon receipt of your shellstock oysters:
  1. The date of harvest;
  2. The location of harvest by state and site;
  3. The quantity and type of shellfish;
  4. The date of receipt; and,
  5. The name of the harvester, the name or registration number of the harvester’s vessel, or an identification number issued by the harvester by the shellfish authority.
  
- You failed to maintain records documenting the following information upon receipt of your shucked oysters:
  1. The date of receipt;
  2. The quantity and type of shellfish; and,
  3. The name and certification number of the packer or repacker of the product.

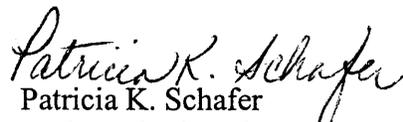
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of your HACCP plans, 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.

Your response should be directed to Mark W. Rivero, Compliance Officer, at the above address.

Sincerely,

  
Patricia K. Schafer  
Acting District Director  
New Orleans District

Enclosure: Form FDA 483