



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Ave.
New Orleans, LA 70122

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March 29, 1999

WARNING LETTER NO. 99-NOL-16

FEDERAL EXPRESS

Mr. Walter A. Trotter/Owner
Coastal State Catering, Inc.
111 Monroe Street
Lafayette, Louisiana 70501

Dear Mr. Trotter:

On December 21 & 23, 1998, an investigator of the Food and Drug Administration (FDA) conducted an inspection of your sandwich manufacturing plant, located at 111 Monroe Street, Lafayette, Louisiana, and documented that your firm was not in compliance with FDA's seafood processing regulations [21 *Code of Federal Regulations* (CFR) 123] and the Current Good Manufacturing Practices (CGMP) requirements for foods (21CFR 110). This causes your finished product, tuna salad sandwiches, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act, in that you failed to operate in accordance with the requirements of 21 CFR123, covering the Processing and Importing of Fish and Fishery Products and the CGMP regulations for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement a preventative 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 "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur. These are the kinds of measures that prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have been fully operating HACCP systems advise us that they benefit from it in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection of your plant, the FDA investigator observed shortcomings in your system that were nearly identical to those pointed out in the April 6, 1998, inspection and stated in the Untitled Letter sent to your firm on June 4, 1998. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 which

presents their evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The observations of concern to us are as follows:

- Failure to have and implement a written HACCP plan for tuna salad sandwiches to address food safety hazards, such as pathogen growth and color additives, that are reasonably likely to occur [21 CFR 123.6(b)]; and,
- Failure to maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed in 21 CFR Part 123.11(b) [21 CFR 123.11(c)].

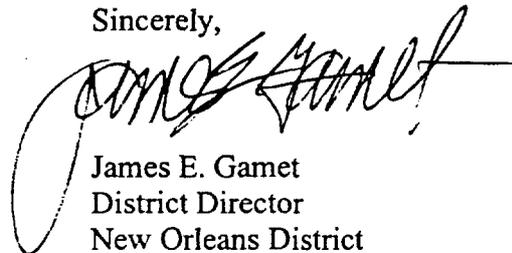
As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies and procedures are implemented to prevent a recurrence of the problems.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the CGMP regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including and explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, LA 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Ms. Hardin.

Sincerely,



James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483