



November 24, 1999

WARNING LETTER 2000-NOL-07**FEDERAL EXPRESS**
OVERNIGHT DELIVERY

Mr. Malcolm A. Jurisich, Owner
Bayou Cook Food Corporation
2515 Iberville Street
New Orleans, Louisiana 70119-5627

Dear Mr. Jurisich:

On May 5, 11, and 12, 1999, investigators with the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood gumbo manufacturing facility, located at 2515 Iberville Street, New Orleans, Louisiana. The investigators documented that your firm was not in compliance with FDA's seafood processing regulations and the Current Good Manufacturing Practices requirements for foods. This causes your finished product, seafood gumbo, 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 Title 21, *Code of Federal Regulations* (CFR), Part 123, covering the Processing and Importing of Fish and Fishery Products and the Current Good Manufacturing Practice (CGMP) regulations for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require that you implement 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 "critical control points" (CCP) 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 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 May 5, 11 and 12, 1999, inspection, FDA investigators observed shortcomings in your system that were similar to those pointed out in the July 28 and 30, 1998, inspection and stated in the untitled letter sent to your firm on August 13, 1998. The FDA investigators also provided your firm with a copy of the Domestic Seafood HACCP Report (Form FDA 3501) and

the Form FDA 483, which presents their evaluation of your firm's performance regarding various aspects of the HACCP and CGMP requirements. The Form FDA 483 is enclosed for your review. The observations of concern to us are as follows:

- ◆ You must have a HACCP plan that lists the critical control points, in order to comply with Title 21, CFR, Parts 123.6(b) and (c)(1). However your firm's HACCP plan for Seafood Gumbo does not list the cook step for the gumbo base as a critical control point for pathogen growth and toxin formation or the labeling step as a critical control point for undeclared sulfites;
- ◆ Failure to consistently implement appropriate record keeping procedures at the CCP of seafood gumbo cook cycle, and component and finished product storage, as required by Title 21, CFR, Parts 123.6(b) and 123.6(c)(7), e.g. the firm did not sign the daily cooking logs or the freezer logs for monitoring storage conditions in the cooler per the firm's HACCP plan;
- ◆ Failure to consistently maintain sanitation control records for May 5, 1999 and May 12, 1999, as required by Title 21, CFR, Parts 123.9(a)(4) and 123.11(c);
- ◆ Failure to adequately monitor sanitation in accordance with Title 21, CFR, Part 123.11(b) as evidenced by:
 - ◆ Water from a sink drain, blocked from draining through a sewer drain, flowed onto the floor in the processing/cookroom. Water from a three-compartment sink overflowed from the drainpipe onto the floor, resulting in two inches of standing water in the room;
 - ◆ The unclean outside surface of the plastic bucket containing cooked gumbo product came into direct contact with the finished gumbo product while the product was transferred from the plastic bucket to aluminum trays. Seafood gumbo product, dripped onto the bucket's exterior, and then dripped into finished product. The bucket was routinely stored on a wet, black-residue stained wooden stool that was stored about six inches off a wet floor with backed-up water. The base of the bucket had wet, brown-colored residues, and was observed being held directly over trays of finished product;
 - ◆ Paddle used to stir finished product was not washed or sanitized;
 - ◆ Plastic trays used to transport trays of finished product contained residues from previous operations; and,
 - ◆ No hand sanitizing solution in the cook room.

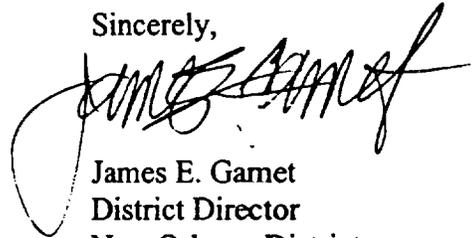
As the principal corporate officer, it is your responsibility to assure that your processing plant is operating in compliance with the applicable laws and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that adequate policies 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 applicable regulations. You should take prompt action to correct these deviations. Failure to promptly correct the deviations may result in regulatory action without further notice. These include seizure and/or injunction.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Our investigators documented this commitment by annotation of the Form FDA 483. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your reply, relating to these concerns, should be addressed to the U.S. Food and Drug Administration, Attention: Patricia K. Schafer, Compliance Officer, 6600 Plaza Drive, Suite 400, New Orleans, Louisiana 70127. If you have any questions regarding the implementation of the HACCP regulations, you may contact Ms. Schafer at (504) 253-4500.

Sincerely,

A handwritten signature in black ink, appearing to read 'James E. Gamet', with a large, sweeping flourish extending from the bottom left of the signature.

James E. Gamet
District Director
New Orleans District

Enclosure: FDA 483