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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
New Orleans District
Southeast Region
4298 Elysian Fields Avenue
New Orleans, Louisiana 70122-3896

Telephone: 504-589-6341
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October 6, 1998

WARNING LETTER NO. 99-NOL-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Paul Albert, Owner
Gulf Coast Seafood, Inc.
280 Oak Street
Biloxi, Mississippi 39530-2624

Dear Mr. Albert:

During an inspection of Gulf Coast Seafood, Inc., 280 Oak Street, Biloxi, Mississippi, conducted on September 21-23, 1998 and October 2, 1998, our investigators documented numerous insanitary conditions in your picked crabmeat operation. This causes your finished product, picked crabmeat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

Objectionable insanitary conditions noted included:

1. At least 30 employees eating crabmeat from cooked crabs, then returning the shells to the cooked crabs;
2. Employee in the cooking/backing room routinely handled insanitary objects, including live crabs, burlap sacks and wood crates containing live crabs, dirty, encrusted trash cans, the electric hoist controls, and a clogged floor drain, then handled cooked crabs without washing or sanitizing their hands;
3. Perforated baskets filled with cooked crabs routinely rested on the dirty, wet floor of the cooking/backing room, which was subject to heavy foot traffic from the live crab processing area;
4. Perforated baskets filled with cooked crabs stored against the walls of the cooking/backing room which was covered with a dark, mold-like material and encrusted residues from previous operations;

5. Baskets used to hold cooked crabs were encrusted with residues from previous operations, and are not washed and sanitized prior to use. Additionally, live ants, flies, and roaches were observed on these baskets prior to their use;
6. No sanitizer solution available for employees throughout the cooking/backing operations;
7. Dirty, encrusted, and inadequately constructed product contact equipment;
8. Baskets of cooked crab claws routinely submerged in a tub filled with a light brown colored liquid which was not changed throughout the cooking/backing operation;
9. Numerous structural defects which could provide for entryways for vermin into the plant;
10. No employees in the cooking/backing room wore protective hair restraints throughout the inspection;
11. Numerous live flies outside and inside the plant on product contact equipment and cooked crabs;
12. Numerous live ants outside and inside the plant on product contact equipment and cooked crabs;
13. Numerous live roaches and spiders on walls and floors throughout the interior of the plant;
14. Employees in the picking/packing room routinely handled insanitary objects, including crab residue-stained wet towels, faces, heads, or clothing, dirty encrusted picking room door, and metal stools, then handled cooked product without washing and sanitizing their hands;
15. On one occasion, an employee retrieved a cooked crab from a trash can and resumed picking meat from the crab body;
16. An employee, on at least five occasions, clearing her throat and spitting into a trash can. During lunch this employee stored a piece of cardboard in this trash can, then returned, retrieved the cardboard from the trash can, placed it on her lap and resumed picking crabs. Another employee retrieved a paper towel from this same trash can, wiped the table and her apron with this paper towel and resumed picking crabmeat in this area;
17. An employee blowing her nose into a paper towel, storing the paper towel on the picking table, then resuming picking crabs without washing and sanitizing her hands;
18. A ceramic drinking cup stored on the picking table during picking operations;
19. A cooked crab retrieved from the picking room floor and replaced on the picking table for further processing;

20. A dirty, encrusted dust pan, picked up from the floor and used to scoop cooked crabs on the picking table;
21. Inadequate hand sanitizers (below 50ppm chlorine) in the picking room;
22. Condensate from cooling units in both coolers falling directly onto cooked crabs; and,
23. Numerous other improper employee practices which could lead to contamination of the firm's finished product.

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 Good Manufacturing Practice 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 an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not 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 Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 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 Mr. Debo.

Additionally, this inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123).

The seafood processing regulations, which became effective on December 18, 1997, require you to 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" in the processing operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures 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 inspection, of your crabmeat picking plant, the FDA investigators observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigators also provided you with a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the FDA-483 which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

- ◆ Failure to have and implement a HACCP Plan as required by 21 CFR Part 123.6(b); and,
- ◆ Failure to provide sanitation monitoring records as required by 21 CFR Part 123.11(c).

Objectionable equipment and insanitary conditions as listed on Form FDA-483 and Form FDA-3501 are an indication that sanitation monitoring [21 CFR 123.11(b)] at the firm is inadequate. Calling your attention to the objectionable insanitary conditions in this letter is in the interest of having your firm improve its sanitation program consistent with the HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions are listed in paragraph two (2) of this letter.

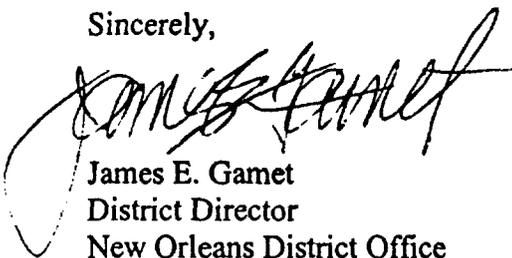
We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these concerns, should be directed to the Food and Drug Administration, Attention: Richard D. Debo, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896. If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mr. Debo at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program in your plant.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", written in a cursive style. The signature is positioned above the printed name and title.

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483

/tjt