



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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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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September 18, 2003

WARNING LETTER NO. 2003-NOL-25

Mr. Terry N. Drawdy, President
Drawdy's Crab Company, Inc.
13965 Shellbelt Road
Bayou La Batre, Alabama 36509

Dear Mr. Drawdy:

We inspected your firm, located at 13965 Shellbelt Road, Bayou La Batre, Alabama, on June 16 - 19, 2003. We found that you have serious deviations from the seafood Hazard Analysis Critical Control Point (HACCP) regulation, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 USC § 342(a)(4). Accordingly, your ready-to-eat crabmeat products are adulterated in that the products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at www.fda.gov <<http://www.fda.gov>>.

The deviations were as follows:

1. You must implement monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not document the temperature of the cooked crabs on June 16, 2003, until 6½ hours after the start of the picking and packing operations. Your HACCP plan for ready-to-eat crabmeat states that the temperature of the crabs during the picking and packing operations will be monitored every _____ to assure the product is maintained at or below _____. A similar observation was noted in our letter to you dated October 24, 2001.
2. You must verify that your HACCP plan for crabmeat is adequate to control food safety hazards that are reasonably likely to occur and that the plan is being implemented effectively to comply with 21 CFR 123.8(a). However, your firm failed to verify that the HACCP plan is being implemented effectively. The dial thermometer you used to monitor the temperature of backed crabs, claws, and picked crabmeat during the picking and packing operations was not calibrated properly on June 16, 2003. A side-by-side comparison of your dial

thermometer with an FDA thermometer was conducted in a cup filled with ice and water. This comparison revealed that your thermometer registered 22°F, and the FDA thermometer registered 32°F. Because your thermometer was recording a temperature 10 degrees lower than the actual temperature, you necessarily would not know when you had exceeded your critical limit of [] at the Picking and Packing critical control point.

Your June 16, 2003, Daily Picking & Packing Log for picked crabmeat on the picking table listed internal product temperatures of 29°, 30°, 39°, 41°, 40°, 40°, 43° and 43°F. In addition, a temperature of 49°F was recorded for crabmeat at a picking station.

Four of the nine temperature measurements listed in your June 16, 2003, Daily Picking & Packing Log exceeded the critical limit of [] when a correction factor of 10°F was added to them. The correction factor takes into account the inaccuracy of your dial thermometer revealed by the side-by-side comparison described above. A corrective action would have been needed for the temperatures of 43° and 49°F if your dial thermometer correctly measured the temperature at 53° and 59°F. Calibrating your thermometers is necessary to ensure you are meeting your critical limits and helps ensure that you are producing a safe product.

3. You must monitor sanitation conditions and practices adequately during processing to comply with 21 CFR 123.11(b).
 - a. Your firm did not monitor adequately the conditions and cleanliness of food contact surfaces, including utensils, gloves, and outer garments as required by 21 CFR 123.11(b)(2). Specifically, your firm’s food processing equipment was not maintained in a sanitary condition to prevent food from becoming adulterated. For example:
 - i. Employees cracking crab claws used several knives that contained a black material encrusted in the etched handles; and,
 - ii. The plastic water plumbing line within the metal crab tumbler contained a brown, slimy substance that contacted cooked crabs during the backing operation.
 - b. Your firm did not monitor adequately the exclusion of pests from the food plant as required by 21 CFR 123.11(b)(8). Specifically, you have not taken effective measures to exclude pests from the processing areas and to protect against the contamination of food on the premises by pests. At least 10 live flies and at least 100 live gnat-type insects landed on cooked crab contact surfaces in the cooking and backing room during processing on June 17, 2003. A similar deviation was noted in our letter to you dated October 24, 2001. Failure to exclude fly pests is a potential contributing factor to microbiological contamination.
 - c. You did not monitor adequately the protection of food, food packaging material, and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other chemical, physical, and biological contaminants as

required by 21 CFR 123.11(b)(5). Specifically, you have not provided safety-type light bulbs over exposed food in any step of preparation to protect against food contamination in case of glass breakage. For example, two of the four light bulbs over the entrance to the cooler in the picking and packing room were not functioning and were not made of a material that resists breakage.

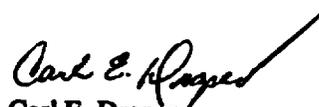
We may take action without further notice if you do not correct these violations promptly. For instance, we may seize your product and/or enjoin your firm from operating. We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within 15 working days from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response your revised HACCP plan, 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 you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

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 Current Good Manufacturing Practice regulations. 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: U. S. Food and Drug Administration, New Orleans District,
Attention: Mr. 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