DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office
g1106d

60 8th Street, N.E.
Atlanta, Georgia 30309

March 30, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Steven Sandler, President
LM Sandler & Sons
P.O. Box 8790
Virginia Beach, VA 23450

Warning Letter
01-ATL-38

Dear Mr. Sandler:

On November 6 - 8, 2000, investigators from the Food and Drug Administration (FDA) conducted an inspection of your plant, Currituck Crab Company, Inc., located at Highway 158 & 168, Barco, North Carolina. During that inspection, our investigators documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to Mr. Grady S. Tillett's attention, cause your fresh, ready-to-eat 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*. Also, during that inspection, we collected several samples consisting of in-line and finished crabmeat processed on 11/6/00 and/or 11/7/00, live and cooked whole crabs, ice and water subsamples, and fifteen environmental swabs from various areas of your plant. We had these samples tested by our laboratory in Atlanta, and found that the finished "BACKFIN BLEND CRABMEAT" (FDA Samples # 115867, 115869, & 115870) packed on both production dates was contaminated with *Listeria monocytogenes*. Based on the findings of FDA samples 115867, 115869 and 115870, crabmeat represented by these samples was adulterated under 402(a)(1) in that they contained *Listeria monocytogenes*, a poisonous and deleterious substance that may render the product injurious to health.

Further, product packed in your facility was adulterated under 402(a)(4) in that it was prepared, packed, and held under insanitary conditions whereby it may have been rendered injurious to health as evidenced by the investigator's observation of condensate dripping from the underside of the cooling unit onto cooked crabs in the cooked crab cooler. FDA sample 105783 shows that condensate from this unit was contaminated with *L. monocytogenes*

The HACCP deviation of concern is as follows:

> 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 condensates with sufficient frequency to ensure control as evidenced by: On 11/6/00, our investigators observed condensation dripping from the underside of a cooling unit on cooked crabs that were stored in the cooked-crab cooler. On 11/7/00, our investigators collected a sample (environmental swab) of the condensate from the underside of the cooling unit referenced above, and submitted it to our laboratory for microbiological analysis. Our laboratory recovered *L. monocytogenes* from this sample (FDA # 105783). This positive finding identifies one of the potential sources of contamination of your crabmeat with *Listeria*.

L. monocytogenes, is a facultative anaerobic (grows in the presence or absence of oxygen) bacterium. The disease listeriosis is caused by the ingestion of this bacterium. All age groups are susceptible to *L. monocytogenes* infections but symptoms are most severe in the elderly, infants, pregnant women, and those people whose immune systems are impaired by medications or illness. The most serious consequence of infections in susceptible individuals is septicemia, when the microorganism enters the bloodstream and actively multiplies. In pregnant women, complications often occur in the fetus and the newborn, resulting in miscarriage, stillbirth, bacteria in the bloodstream of the newborn, or meningitis. In older children and adults, complications commonly involve the central nervous system, pneumonia, endocarditis, localized abscesses, skin lesions, or conjunctivitis. Although listeriosis can be treated with antimicrobial drugs, a significant percentage of people who become sick will die of the illness. For susceptible individuals who become infected, there is a high associated mortality rate that approaches 20%. Therefore, the presence of *L. monocytogenes* in ready-to-eat foods, such as fresh crabmeat, represents a significant danger to public health.

L. monocytogenes can be isolated from soil, silage and other environmental sources and can also be found in man-made environments such as food processing establishments. Any moist area can harbor *L. monocytogenes*. The drier the plant environment, the less likely you are to find the organism.

L. monocytogenes is rare among food-borne pathogenic microbes in that, if nutrients are available, refrigeration is inadequate to prevent growth of *L. monocytogenes*. *L. monocytogenes* has been reported to reproduce in fresh crabmeat, even while refrigerated. Consequently, any *L. monocytogenes* bacteria present in or on crabmeat will continue to reproduce throughout the shelflife of the food.

In the production of commercially processed crabmeat, the crabs are subjected to a cook that based on the heat resistance of *L. monocytogenes*, will destroy the organism. The presence of the organism in the environment provides the opportunity for contamination of the product after the cook. The presence of *L. monocytogenes* in packaged picked crabmeat would be due to post-processing contamination after the cook. Preventing post-processing contamination of fresh crabmeat can only be attained through strict in-plant sanitation programs.

In view of the seriousness of the presence of *L. monocytogenes* in your ready-to-eat crabmeat, we strongly urge you to identify and eliminate the sources of contamination in your plant.

During our previous inspection of your plant on 7/10-11/00, we collected a sample of "Special Crabmeat" packaged on 7/10/00. Microbiological analysis by our laboratory found that product (FDA # 90105) contaminated with *L. monocytogenes*. Although we acknowledge your firm's efforts to recall the affected products, we are very concerned about your firm's apparent inability to prevent contamination of your products with this pathogen.

We may take further action if you do not promptly correct this violation. For instance, we may take further action to seize your product(s) 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 HACCP plans, and HACCP 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 and the FDA 483 (copy enclosed) issued to V. Carlton Ballance, Supervisor, at the end of the inspection 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 Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Grady S. Tillett, General Manager
Currituck Crab Co., Inc.
P.O. Box 328
Barco, NC 27917