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Food and Drug Administration  
Florida District  
555 Winderley Place  
Suite 200  
Maitland, Florida 32751

Telephone: 407-475-4700  
FAX: 407-475-4768

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-08

November 15, 1999

Danny R. Metcalf, President  
Metcalf Crab Company  
51 Ranker Lane  
P.O. Box 627  
Panacea, FL 32327

Dear Mr. Metcalf:

On May 19, 21 and 25, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 51 Ranker Lane, Crawfordville, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the cooked crabmeat processed by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act), as follows:

You must have monitoring records that document the actual values and observations obtained during monitoring in order to comply with 21 CFR 123.6(c)(7). However, you did not have monitoring records to routinely document: the length of cook and minimum temperature at the cooking critical control point, time of exposure to unrefrigerated conditions at the backing and picking critical control points, or adequacy of ice and cooler temperatures at the finished product storage critical control point to control pathogen survival and growth in Processed Blue Crab Meat for a period of time preceding the May 1999 inspection.

You must adequately monitor sanitation conditions and practices during processing in order to comply with 21 CFR 123.11(b). However, your firm did not monitor conditions or practices that could cause cross-contamination from insanitary objects to cooked crabs with sufficient frequency to ensure control. Some of the insanitary practices noted during the production of fresh crabmeat at your firm include:

placing cooked crabs that fell on the floor with other cooked crabs to be processed into crabmeat

employees routinely returning into the picking room from outside the facility and handling unsanitized objects, then resuming handling cooked crabs without washing and sanitizing their hands.

cooked crabs and crab claws routinely coming in contact with dirty plastic milk crates, employees' street clothes, dirty cloth gloves and a handcart also used to transport trashcans.

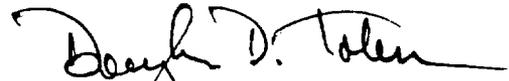
The above-identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,



Douglas D. Tolen  
Director, Florida District