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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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August 22, 2001

WARNING LETTER NO. 2001-NOL-48

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mrs. Margaret C. Waid, President
Comet Crawfish Technology, Inc.
13426 Buckley Avenue
Baton Rouge, Louisiana 70816

Dear Mrs. Waid:

During July 9-10 & 12, 2001, an investigator with the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility, located at 1185 Highway 70 South, Belle Rose, Louisiana. The inspection was conducted to determine compliance with FDA's Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). Our investigator documented deviations from the regulations that could cause your finished products to be adulterated within the meaning 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 homepage at www.fda.gov. The products are as follows:

- Boiled Crawfish Tailmeat in heat-sealed polyethylene bags for refrigeration;
- Boiled Crawfish Tailmeat in vacuum-packed laminated plastic bags for frozen storage;
- Seasoned/Marinated Pasteurized Crawfish Tailmeat in rigid plastic cups with metal lids for refrigeration;
- Seasoned/Marinated Pasteurized Shrimp in rigid plastic cups with metal lids for refrigeration;
- Pasteurized Crab Clawmeat in rigid plastic cups with metal lids for refrigeration;
- Pasteurized Seasoned Crawfish Cheese Spread in rigid plastic cups with metal lids for refrigeration;
- Pasteurized Seasoned Crabmeat Cheese Spread in rigid plastic cups with metal lids for refrigeration;
- Pasteurized Seasoned Shrimp Cheese Spread in rigid plastic cups with metal lids for refrigeration;
- Crab Shell Soup in vacuum-packed plastic bags for frozen storage;
- ██████████ in vacuum-packed plastic bags for frozen storage;
- Crawfish and Sun-dried Tomato Quiche Filling, which includes Pasteurized Crawfish Meat in heat-sealed plastic bags for frozen storage;

- Crab and Broccoli Quiche Filling in heat-sealed plastic bags for frozen storage; and,
- Shrimp and Corn Quiche Filling in heat-sealed plastic bags for frozen storage.

Our investigator provided Mr. Thomas C. Cowsar, Vice-President, with a Form FDA 483 presenting his evaluation of your firm's compliance with applicable aspects of the HACCP requirements. A copy of the Form FDA 483 is enclosed for your reference. Referring to the enclosed copy of the Form FDA 483 issued on July 12, 2001:

- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(c)(1). Your firm's HACCP plans for the seafood quiche products do not list the food safety hazard of the possibility of the introduction of pathogens due to the addition of pasteurized seafood cheese spreads retrieved from retail shelf stock that are beyond your 90-day expiration (or "Best if used by") date. Our investigator observed that your firm routinely retrieves retail shelf stock of your pasteurized seafood cheese spreads that date beyond your 90-day recommended expiration date. You then routinely incorporate this expired product into your seafood quiche products.

However, your firm's HACCP plans for your seafood quiche products do not specifically list the food safety hazard of the presence of food allergens, such as milk, eggs, wheat flour, or sulfites (shrimp product only).

Furthermore, your firm's HACCP plans for pasteurized seafood products do not list the food safety hazard of the possibility of the introduction of pathogens after pasteurization due to contaminated container cooling water.

- You must take appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take corrective action to control cooler temperature when the temperature deviated from your critical limit at the "Store in Cooler" critical control point. Our investigator documented that the temperature in the cooler, during July 5-10, 2001, continuously exceeded your critical limit of 36°F for the storage of pasteurized seafood products. The temperature data obtained from the automatic temperature recorder, during July 5-10, 2001, indicated the average temperature in the cooler was 46.5°F. The temperature range, during the same period, was 41°F to 56°F.

Additionally, our investigator found that on two occasions, the water bath temperature was below the critical limit of 181°F for two consecutive 10-minute measurements during the beginning of the pasteurization process and no corrective action was taken. The temperature of the water bath was 180°F at 10 minutes and 179°F at 20 minutes during the pasteurization process for shrimp spread on March 19, 2001. The temperature of the water bath was 180°F at both the 10 and 20 minute intervals during the pasteurization process of crab claws on February 23, 2001.

- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). Your firm did not follow the monitoring procedure of daily checking refrigerator recording thermometer temperatures at the "Refrigerate" critical control point to control pathogen growth listed in your HACCP plans for pasteurized seafood products. Our

investigator documented that the automatic temperature recorder data records for the refrigerator, also referred to as the cooler, are not reviewed or monitored.

Moreover, qualitative can seam tear down examinations, cited as a critical control point on your HACCP plans for your pasteurized seafood products for refrigeration, were not documented on seaming records for July and August 2000 and March 19, 2001.

Your firm does not have records documenting that finished product labels for your pasteurized seafood products were checked for the declaration of allergenic ingredients as required in your HACCP plans.

- Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate to comply with 21 CFR 123.7(b). However, your corrective action plans for your pasteurized seafood products at the critical control point of refrigerated storage of finished products to control pathogen growth is not appropriate. The HACCP plans do not address correcting elevated refrigerator temperatures.
- You must verify that your HACCP plan is adequate to control food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.8(a). There are no verification records available regarding the establishment of any of your pasteurization processes for any of your pasteurized products.

Your firm did not identify the target pathogen(s) for any of your pasteurization processes for any of your pasteurized products.

- You must retain records at the processing facility for at least one (1) year after the date the refrigerated products were prepared to comply with 21 CFR 123.9(b)(1). However, your firm did not have pasteurization records for all pasteurized seafood products produced between September 1, 2000 and January 31, 2001, and pasteurized Mediterranean-style crawfish tailmeat manufactured on May 28, 2001.

In addition, your firm did not have the can seam examination records for your pasteurized seafood products for refrigeration, manufactured since September 1, 2000.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your processing plant is operating in compliance with applicable requirements and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We are aware that on July 10, 2001, Mr. Cowsar provided our investigator a signed voluntary destruction statement. Our investigator observed, on July 10, 2001, swollen containers of pasteurized crawfish tailmeat. Mr. Cowsar voluntarily destroyed this lot consisting of 10 cases (60 pounds in total) of pasteurized crawfish tailmeat on July 10, 2001. Additionally, on July 12, 2001, Mr. Cowsar told our investigator he decided to destroy all product observed stored in your

firm's cooler on July 10, 2001, due to temperature abuse. This included all pasteurized crawfish, crab, and shrimp products present in the cooler.

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 taken to prevent the recurrence of similar violations. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Rebecca A. Asente, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: Form FDA 483