



May 24, 2001

WARNING LETTER NO. 2001-NOL-24

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Emile L. Desporte, III, President
Desporte and Sons Seafood, Inc.
444 Caillavet St.
Biloxi, Mississippi 39530-2050

Dear Mr. Desporte:

We inspected your firm, located at 444 Caillavet St., Biloxi, Mississippi, on April 24 and 25, 2001, and found that you have serious deviations from Seafood HACCP regulations Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention during an inspection conducted at your firm on March 8-9, 2000, cause your crawfish products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth. You can find this Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations were as follows:

- You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for cooked crawfish does not list a critical limit for time or temperature at the post cooking "critical control point" to control the hazard of pathogen growth and toxin formation.
- You must have a HACCP plan that lists monitoring procedures for each "critical control point," to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for cooked crawfish does not list the time or temperature monitoring procedure at the cooking step to control the hazard of pathogen survival. In addition, your firm's HACCP plan for cooked crawfish does not list the time or temperature monitoring procedure at the post cooking critical control point to control the hazard of pathogen growth and toxin formation.
- 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). However, your firm's HACCP plan for cooked crawfish does not list food safety hazards of aquaculture drugs and environmental chemicals.

- You must take an appropriate corrective action when a deviation from a critical limit (CL) occurs, in order to comply with 21 CFR 123.7(a). However, your firm did not take a corrective action to control pathogen survival when your process for cooked crawfish did not reach ██████████ and deviated from your CL at the cooking “critical control point.”

We may take further action if you do not promptly correct these violations. 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 your revised HACCP plan 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 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 110). 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 the Food and Drug Administration, Attention: 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,



Howard E. Lewis
Acting District Director
New Orleans District

Enclosure: Form FDA-483