



Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, FL 32751

VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-08

November 9, 2001

Thomas B. Seigle, President  
Landshire of Florida, Inc.  
18630 N.E. 2<sup>nd</sup> Avenue  
North Miami Beach, Florida 33179

Dear Mr. Seigle:

We inspected your seafood sandwich processing plant, located at the above address, on June 19, 21 & 22, 2001 and found that you continue to have serious deviations from the Seafood Processing (HACCP) Regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and these regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You must implement the record keeping system listed in your HACCP plan for tuna salad sandwiches, to comply with 21 CFR 123.6(b). However, your firm did not record temperature monitoring observations from January through June 2001 at the receiving and storage critical control points to control the food safety hazard of pathogen growth and toxin formation as a result of time/temperature abuse. This deviation was previously brought to your attention at the close of our September 27, 2000 inspection.

You must maintain sanitation control records that document monitoring and corrections of sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(c). However, no sanitation control records are maintained by your firm to show that plant water safety, cleanliness of food contact surfaces, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from adulterants, proper labeling, storage and use of toxic compounds, control of employee health conditions and exclusion of pests are monitored with sufficient frequency to ensure control. This deviation was previously brought to your attention at the close of our September 27, 2000 inspection.

Several objections to sanitation were also documented by the investigator during the inspection that included: employees not wearing hair restraints; employees not washing and sanitizing their hands after touching insanitary objects during production; old dried food residues on the walls and floors under preparation tables in the food preparation area; and chemicals and lubricants being stored in the food preparation area.

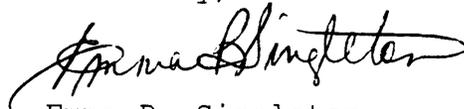
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

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 your HACCP plan, sanitation control 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 may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act, the Seafood Processing (HACCP) Regulations and the Good Manufacturing Practice (GMP) Regulations for foods (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 the Food and Drug Administration, Attention: Jimmy E. Walthall, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Mr. Walthall at (407) 475-4731.

Sincerely,



Emma R. Singleton  
Director, Florida District