

**VIA FEDERAL EXPRESS**Food and Drug Administration  
555 Winderley Pl., Ste. 200  
Maitland, Fl 32751**WARNING LETTER**

FLA-01-03

October 10, 2000

Luz M. Rubio, President  
Tasty Foods Place, Inc.  
2551 West 3<sup>rd</sup> Avenue  
Hialeah, Florida 33010

Dear Mrs. Rubio:

We inspected your seafood sandwich manufacturing plant on April 3-4, 2000 and found that you continue to have a serious deviations from the seafood (HACCP) regulations (21 CFR Part 123). These deviations cause your tuna fish salad, tuna fish sandwiches and whiting fish filet sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic 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 are as follows:

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 whiting cooked breaded fish filet sandwiches does not list the food safety hazard of pathogens.

You must have a HACCP plan that list all appropriate critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for whiting cooked breaded fish filet sandwiches does not list batter/breading and finished product storage as critical control points for controlling the food safety hazard of pathogens and toxin formation.

You must have a HACCP plan that list monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for whiting cooked breaded fish filet sandwiches does not list the monitoring procedure for what is to be monitored, who does the monitoring, and the frequency of the monitoring. In addition, your firm's HACCP plan for Tuna Fish Products does not list what is to be monitored and who does the monitoring.

Luz M. Rubio  
Page 2  
October 10, 2000

You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at the cooking critical control point to control pathogen growth and toxin formation for whiting cooked breaded fish filet sandwiches. In addition, your HACCP plan for whiting cooked breaded fish filet sandwiches does not list the record where monitoring could be recorded.

You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm is not monitoring sanitation conditions with sufficient frequency to ensure control as evidenced by: no hot water available at hand wash sinks; no hand cleanser available in the women's restroom; no back flow prevention devices on hoses; unlabeled bleach found in a food preparation area; standing waste water in the kitchen area; inadequate storage practices; inadequate cleaning procedures; unclean equipment; and litter on the grounds around the facility. These conditions are also serious deviations from the Good Manufacturing Practice (GMP) regulations for foods (21 CFR 110).

You must have sanitation control records that document the monitoring and corrections of sanitation conditions during processing, in order to comply with 21 CFR 123.11(c). However, sanitation control records are not being maintained.

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 (HACCP) regulations and the Good Manufacturing Practice (GMP) regulations for foods. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations. We may take further action if you do not promptly correct these violations. For instance, we may 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 violations. You may wish to include in your response documentation such as a copy of your revised HACCP plan for whiting fish filet sandwiches, examples of monitoring records, sanitation control records or other useful information that would assist us in evaluating your corrective action. If you cannot complete correction before you respond, we expect that you will explain the reason for your delay and state when you will correct this deviation.

Luz M. Rubio  
Page 3  
October 10, 2000

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,



*for*

Emma R. Singleton  
Director, Florida District