

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

FLA-00-54

May 8, 2000

James L. Robinett, President
Gulf Go-Fers, Incorporated
2136 Corporation Boulevard
Naples, Florida 34106

Dear Mr. Robinett:

We inspected your sandwich manufacturing plant on April 26-27, 2000 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, which were previously brought to your attention, cause your ready-to-eat tuna salad 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.

The deviations are as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for your ready-to-eat tuna salad sandwiches to control the potential food safety hazard of pathogens. This deviation was previously brought to your attention in our letter of December 6, 1999.

You must have 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 in our letter of December 6, 1999.

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We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your ready-to-eat tuna salad sandwiches 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 for ready-to-eat tuna salad sandwiches, 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 HACCP regulations and the Current Good Manufacturing Practice (CGMP) 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,



Edward R. Atkins
Acting Director
Florida District