



**VIA FEDERAL EXPRESS**

**WARNING LETTER**

**FLA-02-38**

April 26, 2002

Joseph A. Villers, President  
R. H. V. Inc.  
D/b/a Villers Seafood  
1200 Main Street  
Fort Myers Beach, Florida 33931

Dear Mr. Villers,

We inspected your firm, located at 1200 Main Street, Fort Myers Beach, Florida 33931 on September 7, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh bulk and frozen retail shrimp to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in the FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

You must have a HACCP plan that lists the critical control points, to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for fresh shrimp does not list the critical control point of labeling to control the food safety hazard of sulfites.

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 fresh shrimp lists a critical limit of "Residual on edible portion less than 100 ppm" at Receiving and Unloading that is not adequate to control the food safety hazards of sulfites, in that your firm does not perform sulfite testing on fresh shrimp received, as specified in your HACCP plan.

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 fresh shrimp does not list any monitoring procedures to control the hazard of sulfites.

You must retain records at the processing facility for at least one year after the date they were prepared in the case of refrigerated product, to comply with 21 CFR 123.9(b)(1). However, your firm's labeling records for fresh shrimp were not retained.

Our review of your retail (5 pound) box label for shrimp reveals that the product is misbranded in that the boxes fail to bear the name and place of business of the manufacturer, packer, or distributor as required by Section 403(e)(1) of the Act and 21 CFR 101.5(a).

Our review of your fresh bulk label for shrimp reveals that the product is misbranded in that the label states the product may contain sodium bisulfate although you are able to control or determine whether the sulfites are present as required by Section 403(i)(2) of the Act and 21 CFR 101.4(a).

If you set the critical control point for sulfiting agents at the finished product labeling step, and intend to label all finished product with a sulfiting agent declaration, you should revise your HACCP plan to reflect this practice rather than testing at the raw material receiving step. Such a HACCP plan should also reflect appropriate monitoring and record keeping for the critical control point at the finished product labeling step.

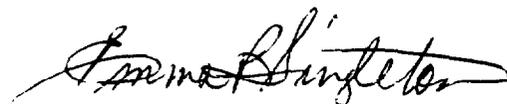
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. In addition, we may not provide certificates to your firm for export of your products to European Union (EU) countries if you do not correct these deviations.

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 and monitoring 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 the 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 Part 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: Shari J. Hromyak, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida 32751. If you have questions regarding any issue in this letter, please contact Ms. Hromyak at (407) 475-4730.

Sincerely,



Emma R. Singleton  
Director, Florida District