



VIA FEDERAL EXPRESS

WARNING LETTER

FLA-02-40

May 8, 2002

Jorge J. Pujol, President
Pujol & Valancy, Inc.
D.b.a. Flamingo Seafood
3199 N. W. 20th Street
Miami, Florida 33142

Dear Mr. Pujol:

We inspected your firm at the above address on December 20, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). The deviations cause your imported frozen lobster tails 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 homepage at www.fda.gov.

Although all of your product labels declare sulfites, our investigator determined that frozen lobster tails containing sulfiting agents may be imported and shipped without repackaging, resulting in a possibility that packaged lobster tails may enter commerce without the necessary declaration of sulfites.

The deviations that relate to this hazard are as follows:

1. You must have product specifications that are designed to ensure that the fish and fishery products you import are not adulterated under Section 402 of the Act because they may be injurious to health or have been processed under insanitary conditions, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have written specifications for the frozen spiny lobster products imported from Jamaica. The documents your firm presented from [REDACTED] states that sulfites may be used during processing. You must have product specifications that ensure that any inclusion of sulfites is declared in the labeling on these imported products.
2. You must implement an affirmative step, which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations to comply with 21 CFR 123.12(a)(2)(ii). Your firm has stated to FDA that your affirmative step consists of maintaining on file foreign processors' HACCP plans for lobster tails from [REDACTED]. FDA has reviewed these documents and determined that they do not appear to be HACCP plans and, in any event, are not adequate. Neither firm's document identifies the potential food safety hazard of undeclared sulfiting agents. Moreover, under 21 CFR 123.12(a)(2)(ii)(D), in additio

to maintaining the foreign HACCP plans on file, you must maintain on file a written guarantee from each foreign processor stating they are operating in compliance with 21 CFR 123. You have no written guarantee from [REDACTED] and the written guarantee from [REDACTED] fails to include this statement. The lack of adequate affirmative steps was also brought to your attention in a previous letter dated September 2, 1998.

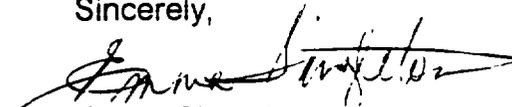
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the U.S. Federal Food, Drug, and Cosmetic Act and all applicable statutes.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your aforementioned products and/or enjoin your firm from operating. In addition, the FDA may detain your imported seafood products without examination. Under such conditions, the FDA will not issue any Certificates for Export or European Union Health Certificates for any of the affected fish and fishery products processed at your facility.

Please respond in writing within three (3) weeks of your receipt of this letter. Your response should outline the specific steps you are doing to correct these deviations. You may wish to include in your response documentation such as amended HACCP plans, revised forms, or other useful information that would assist us in evaluating your corrections. If you are unable to complete all of the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund, Compliance Officer, 555 Winderley Place, Suite 200, Maitland, Florida, 32751. If you have any questions regarding any issue in this letter, please contact Ms. Englund at (407) 475-4741.

Sincerely,



Emma Singleton
District Director
Florida District Office