



JAN 3 2001

Mr. Miguel Renan Solis Molina  
Inpesmar I, S.A.  
Calle 12, No. 19  
Celestum, Yucatan, Mexico

**WARNING LETTER**

Dear Mr. Miguel Renan Solis Molina:

We inspected your firm, located at Calle 12, No. 19 Celestum, Yucatan, Mexico, on August 7-8, 2000 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 Grouper, and Snapper 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 FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations were as follows:

1. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of documenting the harvest area of the ciguatoxin-associated species you receive at the Receiving critical control point to control the hazard of CFP (ciguatoxic poisoning) listed in your HACCP plans for **Whole and Fillet Fish - Iced & Frozen**.

Please respond in writing within six (6) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. If you believe the hazards listed above are not reasonably likely to occur in your products, you must provide U.S. FDA with adequate, written documentation that clearly supports your reasoning. You may wish to include in your response documentation such as corrected HACCP plans, completed 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 your delay and state when you will correct any remaining deviations. Failure to provide us evidence of corrections to the deviations may result in your products being placed on "Detention Without Physical Examination."

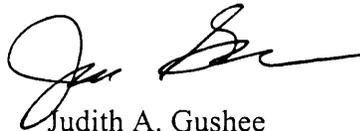
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures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

Please send your reply to the following address:

Mr. Brian Landesberg  
Import Branch, HFS-606  
Division of Enforcement and Programs  
U.S. Food and Drug Administration  
200 C. Street, S.W.  
Washington, DC 20204

If you have any questions regarding any issue in this letter, please contact Mr. Landesberg at (202 ) 205-5247.

Sincerely,

A handwritten signature in black ink, appearing to read "Judith A. Gushee". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Judith A. Gushee  
Director  
Division of Enforcement and Programs  
Office of Field Programs  
Center for Food Safety  
and Applied Nutrients