



DEPARTMENT OF HEALTH AND HUMAN SERVICES

6/8/99

HFI-35

Public Health Service

m26807

Food and Drug Administration
Florida District
555 Winderley Place
Suite 200
Maitland, Florida 32751

Telephone: 407-475-4700
FAX: 407-475-4769

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-63

May 18, 1999

Ramon E. Placeres, President
Placeres & Sons Seafood, Inc.
2275 West 9th Avenue
Hialeah, Florida 33010

Dear Mr. Placeres:

On January 20-21, 1999, the Food and Drug Administration (FDA) conducted an inspection of your seafood importing and repacking facility. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing the seafood products being imported, repacked, and stored by your firm to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), as follows:

Domestic Operation

Failure to have a written HACCP plan(s) in English and to fully implement the plan(s) to control potential food safety hazards that are reasonably likely to occur in seafood products received, repacked, and stored by your firm [21 CFR 123.9(c)].

Failure to maintain accurate sanitation control records [21 CFR 123.11(c)] that document the monitoring and corrections during processing of sanitation conditions specified in the regulations, for example, plant water/ice 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 [21 CFR 123.11(b)].

Import Operation

Failure to establish product specifications that are designed to ensure that seafood products are processed in accordance with the requirements of the HACCP regulation, for example, frozen conch meat imported from Jamaica [21 CFR 123.12(a)(2)].

Failure to ensure that the HACCP plan for imported frozen conch meat provided to your firm by [REDACTED] is adequate. For example, the plan fails to list potential hazards, critical control points, critical limits, monitoring procedures and corrective action plans [21 CFR 123.6(c)].

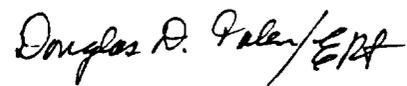
The above identification of violations are not intended to be an all-inclusive list of deficiencies at your importing, repacking, and storage facility. It is your responsibility to ensure that all seafood products received, repacked, stored, and distributed by your firm are in compliance with the Act and the requirements of the regulations.

You should take prompt action to correct these and all violations at your firm. Failure to achieve correction may result in further regulatory action without further notice. These actions may include seizure, injunction, or removal from the European Union (EU) list. Additionally, until FDA is satisfied that the above deficiencies have been corrected, no EU certificates will be issued. In addition, FDA may detain your imported seafood products without examination until compliance with the seafood regulations is achieved and verified.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. You should include copies of any documentation with your response demonstrating that corrections have been made. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,



Douglas D. Tolen
Director, Florida District