



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

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10/20/98
M21847

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-02

October 1, 1998

Daniel R. Leonard, Vice-President
Leonard Shrimp Products, Incorporated
1058 Island Avenue
Tarpon Springs, Florida 34689

Dear Mr. Leonard:

On August 20, 1998, the Food and Drug Administration (FDA) conducted an inspection of your shrimp processing plant. The investigator documented serious deviations from the seafood processing regulations in Title 21 Code of Federal Regulations, Part 123 (21 CFR 123) causing shrimp processed 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:

Failure to have and implement a written HACCP plan for the shrimp processed by your firm to control the food safety hazard of sulfites that is reasonably likely to occur [21 CFR 123.6(b)].

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, prevention of cross-contamination, maintenance of hand sanitizing facilities, protection from adulterants, and proper labeling, storage, and use of toxic compounds [21 CFR 123.11(b)].

In addition, your proposed sanitation control record obtained during the inspection fails to include the name of your firm, the date and time of the activity that the record reflects, and the signature or initials of the person performing the operation [21 CFR 123.9(a)].

The above identification of violations are not intended to be an all-inclusive list of deficiencies at your processing plant. As vice-president, it is your responsibility to ensure that all seafood products processed 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 violations. Failure to correct these violations may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA will not issue any certificates for export of any seafood products processed by your firm until full compliance with the seafood regulations is achieved.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct these violations and to prevent their reoccurrence. Your response should include copies of any documentation 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,

A handwritten signature in black ink that reads "Douglas D. Tolen". The signature is fluid and cursive, with a long horizontal stroke at the end.

Douglas D. Tolen
Director, Florida District