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Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

M22091



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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-99-12

November 19, 1998

Chong K. Shin, President
Eastern Treats, Inc.
5626 Hansel Ave.
Orlando, FL 32809

Dear Mr. Shin:

On September 29-30, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 5626 Hansel Ave., Orlando, FL. The investigator documented deviations from the Seafood HACCP Regulation in Title 21, Code of Federal Regulations, Part 123 (21CFR 123), causing the seafood products 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 to control the potential food safety hazards that are reasonably likely to occur with shrimp egg rolls manufactured by your firm, e.g., presence of sodium bi-sulfites and metal inclusion [21 CFR 123.6(b)].

Failure to adequately monitor all of the sanitation controls required in 21 CFR 123.11(b) or maintain sanitation control records [21 CFR 123.11(c)] that document the monitoring and correction of sanitation conditions specified in the regulations, for example, plant water and ice safety, prevention of cross-contamination, maintenance of hand washing, hand sanitizing, and toilet facilities, protection from contaminants, proper labeling, storage, and use of toxic compounds, control of employee health conditions, and exclusion of pests.

Your firm is also in violation of 21 CFR 123.6(a) for failure to conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of fish and fishery product received and processed by your firm and to identify the preventive measures that can be applied to control those hazards.

In addition, your finished product shrimp egg roll packages are in violation of Section 403 (i) of the Act in that they fail to declare the ingredient sulfites and its function in the product [21 CFR 101.22(j)] or to list all of the ingredients in descending order of predominance by weight, since shrimp is not listed as an ingredient [21 CFR 101.4(a)(1)].

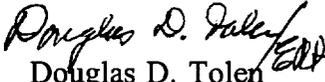
The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct the deviations noted 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 of the seafood products processed at your facility until your firm is fully in compliance with the Seafood HACCP regulation.

Please 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, including an explanation of each step taken to prevent their reoccurrence. Your response should include copies of any available 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 the corrections will be completed.

Your written reply should be directed to Ken Hester, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4730.

Sincerely,


Douglas D. Tolen
Director
Florida District