DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Cincinnati District

g1286d

Food & Drug Administration
6751 Steger Drive
Cincinnati, OH 45237-3097

May 23, 2001

WARNING LETTER
CIN-WL-01-7913-0

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Thomas M. Patterson, Owner
Foremost Seafood
1904 Woodman Center Drive
Kettering, OH 45420

Dear Mr. Patterson:

We inspected your firm located at the above address on May 2-3, 2001 and found that you have serious deviations from the Seafood HACCP regulations, Title 21 Code of Federal Regulations, Part 123). These deviations, some of which were previously brought to your attention, cause your frozen and fresh seafood products e.g., your mahi mahi fish products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations on the Internet through links in FDA's home page at www.fda.gov.

Your firm must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur (21 CFR 123.6(b)). For example, your firm does not have a HACCP plan for your mahi-mahi fish products to control Scombrotoxin (Histamine) formation. This deviation was previously brought to your attention in our letter to you dated September 27, 2000. You should consider using the booklet, *Fish & Fisheries Products Hazards & Controls Guide, Second Edition* to better understand the food safety hazards associated with each of the fish products your firm processes. The booklet is a FDA, CFSAN, Office of Seafood publication that is available at the FDA Internet site: http://vm.cfsan.fda.gov/~dms/haccp-2.html.

We may take further action if you do not promptly correct the violation. We may for instance take further action to seize your products and/or enjoin your firm from operating.

The FDA inspection also revealed that your firm's food processing area does not appear to be adequate to permit the taking of proper precautions to reduce the potential for contamination of food, food-contact surfaces or packaging materials with microorganisms, chemicals, filth, or other extraneous material. For example, equipment used in the processing of the fish is constructed of wood, which can not be easily cleaned and sanitized. In addition, fish processing occurs in the loading dock area that appears to lack adequate means for environmental and pest control.

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 respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you have taken to correct these deviations. 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.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District