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DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35
Public Health Service
Food and Drug Administration m2688m

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St. Louis, Missouri 63143-3800
(314) 645-1167, (314) 645-2969 FAX

June 8, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Jeffry P. Melchert
President
Great Midwest Seafood Co.
5406 N. Sheridan St.
Davenport, IA 52806

Re: STL-99-04

Dear Mr. Melchert:

An inspection of your firm on March 26-30, 1999, by a Food and Drug Administration Investigator from this office revealed molluscan shellfish, smoked fish, and pickled fish are processed at, and distributed from, your facility under serious deviations from Title 21, Code of Federal Regulations (21 CFR), Part 123. These deviations cause these products to be adulterated under Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (The Act).

As we explained in a previous letter to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed your processing of molluscan shellfish, smoked fish, and pickled fish deviates from the regulations contained 21 CFR Part 123 summarized as follows:

1. Failure to adequately apply appropriate corrective action(s) for refrigerated raw products as required by 21 CFR 123.7 (a)(2). For example, there was no corrective action(s) for those products which exceeded the critical limit of 42 degrees F on 8/28/98, 9/12/98, 10/26/98, 1/5/99, and 1/26/99.
2. Failure to develop and implement a written HACCP Plan for frozen molluscan shellfish, smoked fish, and pickled fish as required by 21 CFR 123.6 (b).
3. Failure to list appropriate critical limit(s) that must be met at receiving and the production cooler storage critical control points to prevent, eliminate, or reduce to an acceptable level the occurrence of natural toxins and pathogen formation in your HACCP plan for raw refrigerated molluscan shellfish as required by 21 CFR 123.6(c)(3).
4. Failure to monitor appropriate tagging or labeling on fresh molluscan shellfish.

You need to develop HACCP programs to address all the safety hazards associated with frozen molluscan shellfish, smoked fish, and pickled fish. You did send in HACCP plans addressing these three products, however, the plans are inadequate. The molluscan shellfish HACCP plan did not properly identify the significant hazards of pathogens and natural toxin formation. The smoked fish/pickled fish HACCP plan did not address the critical limits for the primary processing control barriers to C. botulinum and other pathogens in these products, such as acidity (pH) and salt level (water activity). Also, the corrective action for the critical control point of cooling storage just states "cooler" which is insufficient. It must specify an acceptable temperature. In addition, you are not following the molluscan shellfish HACCP plan procedure at the receiving step.

This letter is not intended to be all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA-483, Inspectional Observations, which is a list of the investigator's observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

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Great Midwest Seafood Co.

Your reply should be sent to Andrew H. Paeng, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers". The signature is written in a cursive style with a long horizontal stroke at the end. It is positioned over a dark, textured rectangular area that looks like a stamp or a shadow.

W. Michael Rogers
District Director
Kansas City District