



DEPARTMENT OF HEALTH AND HUMAN SERVICES

FB 10/11/00
Food and Drug Administration
Kansas City District
Southwest Region
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

October 10, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**WARNING LETTER
KAN #2001-005**

John A. Mann, Owner
Mann's Fish Market
East 7th & 20th Street
Route 2, Box 185
Caruthersville, MO 63830

Dear Mr. Mann:

We inspected your firm located at the above address on May 15 & 16, 2000, and found that you have serious deviations from Title 21 of the Code of Federal Regulations Part 123 (21 CFR 123) – Fish and Fishery Products (Seafood HACCP regulations). A Form FDA 483 listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your salted river fish roe 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 through links in FDA's homepage at www.fda.gov.

Our inspection revealed your processing of salted river fish roe deviates from the regulations contained in 21 CFR Part 123 as follows:

- Failure to have an adequately written HACCP plan to control any food safety hazards that are reasonably likely to occur [21 CFR 123.6]. Your HACCP plan for salted river fish roe does not include:

Records to verify the addition of ½ ounce of salt per pound of roe, as outlined in your HACCP plan.

Documentation which would verify that the addition of ½ ounce of salt per pound of roe results in the 10% water phase salt concentration that is required for the control of temperature abuse pathogens.

Documentation to verify the accuracy of the digital thermometers used to check the temperature of the storage cooler used for roe.

- Failure to maintain sanitation monitoring and control records for [21 CFR 123.11(c)], as evidenced by:

Lack of back flow prevention devices on water hoses located in the roe processing room.

Old fish residue adhering to the ceiling directly above fish cutting table.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

On June 12, 2000 we sent you a letter asking what steps you had taken to correct the deviations noted during our inspection. We have not received a response to that letter.

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.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



for Charles W. Sedgwick
District Director
Kansas City District