



May 23, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

**WARNING LETTER
Ref. KAN 2001-024**

Edward Kram, Owner
Kram Fish Company
1307 Biddle
St. Louis, MO 63106

Dear Mr. Kram:

We inspected your firm located at the above address on March 12-14, 2001, 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 processed catfish, carp and buffalo fish 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 fresh water fish deviates from the regulations contained 21 CFR Part 123 as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm has not prepared and implemented a HACCP plan for carp, catfish or buffalo fish. This deviation was previously brought to your attention in our letter dated May 27, 1998.

You must have an adequately trained or qualified individual in order to comply with 21 CFR 123.11(b), who can implement and review the HACCP plan.

Other objectionable conditions were brought to your attention and listed on the Form FDA 483, Inspectional Observations, issued to you at the conclusion of the inspection. These observations included unshielded lights, residue buildup on processing equipment, walls and ceilings, processing equipment contacting the floor, employees eating and drinking in processing areas, and pooling water containing processing debris. Many of these deviations were previously brought to your attention in our letter dated May 27, 1998.

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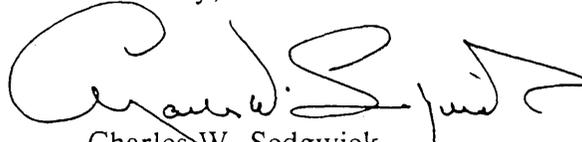
This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as your revised HACCP plan and copies of your monitoring records, or other useful information that would assist us in evaluating your corrections. 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.

Please send your reply to the Food and Drug Administration, Attention: Clarence R. Pendleton, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Pendleton at (913) 752-2103.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles W. Sedgwick". The signature is fluid and cursive, with a large initial "C" and a long, sweeping tail.

Charles W. Sedgwick
District Director
Kansas City District