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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

September 20, 2000

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

WARNING LETTER

Ref. KAN-2000-030

Mr. Walter M. Queen, President
Coldwater Fish Farms
Box 11700 Guinotte
Lisco, Nebraska 69148

Dear Mr. Queen:

On August 29 – 31, 2000, we conducted an inspection of your fish farm in Lisco, Nebraska. The investigator documented deviations from the Seafood Hazard Critical Control Point (HACCP) Regulations in 21 Code of Federal Regulations part 123 [21 CFR 123], and the Current Good Manufacturing Practice (CGMP) regulations for foods 21 CFR 110. These deviations cause 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).

Deviations noted include the following:

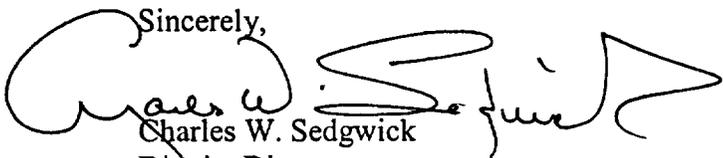
1. The HACCP plan for hot smoked salmon and trout does not adequately control the clostridium botulinum hazard associated with the product. The plan does not identify brining, smoking, cooling and finished product storage as critical control points. [21 CFR 123.6(c)(2)]
2. The written HACCP plan for fresh/frozen salmon and trout does not indicate the critical limits for aquaculture drugs. [21 CFR 123.6(c)(3)]
3. The current HACCP plans are not signed or dated. [21 CFR 123.6(d)]
4. Cross contamination monitoring for employees is not performed during processing or frequently enough to protect products against contamination. [21 CFR 123.11 (b)]
5. Time and temperature records did not indicate the product and cooler temperatures after the smoked fish was removed from the smoker. Records were also not dated. [21 CFR 123.9(a)(4)]
6. Temperature recording charts for the smokehouse time/temperature record does not indicate the smoked fish was held at required time and temperature. [21 CFR 123.6(c)(7)]

7. Monitoring for conditions and cleanliness of food contact surfaces is inadequate. [21 CFR 123.11(b)]
8. The calibration method for thermocouple in the smoker unit is not adequate. [21 CFR 110.40 (f)]
9. An employee conducting sanitation monitoring demonstrated a lack of knowledge and/or training to determine if conditions and practices were appropriate to ensure sanitation control. [21 CFR 110.10(c)]

The above observations 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 action to correct these violations and establish appropriate procedures that will prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

We request a response to this letter within fifteen (15) days addressing any procedures implemented. Include in your response any corrective actions you have taken or plan to take and have yet to complete. All the items stated in your response will be verified during our next inspection. If you have further questions or concerns, you should reply directly to Monica R. Maxwell, Compliance Officer, at the above address.

Sincerely,

Charles W. Sedgwick
District Director
Kansas City District