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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
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August 14, 2000

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 00 - 46

Andrew LaFond
Owner
LaFond Fisheries
Shanty Row, E5763 Jefferson Road
Algoma, Wisconsin 54201

Dear Mr. LaFond:

We inspected your firm located at E5763 Jefferson Road, Algoma, WI, on March 14, 2000, and found that you have serious deviations from the seafood HACCP regulations, Title 21, Code of Federal Regulations, Part 123, and Good Manufacturing Practice regulations, Part 110 (21 CFR 123 and 110). These deviations, some of which were previously brought to your attention, cause your salted fish roe 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 through links at FDA's internet Home Page at www.fda.gov.

The following deviations were noted at your fish roe processing and storage operations:

1. You must implement the record keeping system listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations:
 - a. At the draining critical control point (CCP2) to control the hazard of pathogen growth (bacteria) listed in your HACCP plan for chub roe (caviar).
 - b. At the Refrigeration/Storage critical control point to control the hazard of pathogen growth (bacteria) listed in your HACCP plan for chub roe (caviar).
2. You must have a HACCP plan that lists the critical control points for each of the identified food safety hazards to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for chub roe (caviar) does not list the critical control point of Salting to control the food safety hazard of

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Clostridium botulinum. You must verify that your salting process provides an adequate water phase salt level and pH to control this pathogen and implement regular verification testing to assure that your process continues to be adequate.

3. You must have sanitation control records that document monitoring and corrections to comply with 21 CFR 123.11(c). However, your firm did not maintain sanitation control records.
4. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor processing water quality with sufficient frequency to ensure its potability. As of our last inspection on March 14, 2000, you had not tested your well water in over a year. Your last safe well water report, at the time of our inspection, was dated January 30, 1999.

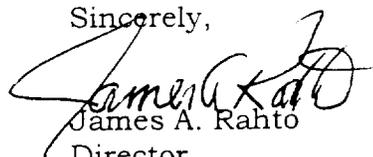
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your products and/or enjoin your firm from operating. In addition, we may not provide certificates for your firm to export your products to  countries if you do not correct these deviations.

Please respond in writing within three 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 or other useful information that will assist us in evaluating your corrections. If you cannot complete your corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining deviations.

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 of 21 CFR 123 and the Good Manufacturing regulations of 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead. If you have questions regarding this matter please contact Mr. Nelson at (612)334-4100 ext. 177.

Sincerely,



James A. Rahto
Director

Minneapolis District

TPN/ccl