DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

COPY

May 18, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-18

Richard Yoshimura, President
Mutual Fish Company
2335 Rainier Avenue South
Seattle, Washington 98144

WARNING LETTER

Dear Mr. Yoshimura:

On February 18 and 19, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 2335 Rainier Avenue South, Seattle, Washington. At the conclusion of the inspection, Kevin C. Yoshimura, Vice President, was presented with a FORM FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that FORM FDA 483 is enclosed for your review. By virtue of these deficiencies, the hot smoked salmon manufactured by your firm is adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

The observations of concern to us are listed below.

1. Failure to list appropriate critical limits for each critical control point as required under 21 CFR Part 123.6(c)(3), for example:

   a. The cook time was not listed as a critical limit in the HACCP plan.

   b. The brine time was not listed as a critical limit in the HACCP plan.

2. Review of your private laboratory testing records for finished product found that the percent water phase salt is not consistently 2.5% or higher. As it applies to your firm, the definition of a critical limit, under 21 CFR Part 123.3(c), is a parameter that must be met to prevent the occurrence of *Clostridium botulinum* growth and toxin formation. Air packed product must have a water phase salt of 2.5% or higher to control for the food safety hazard of *Clostridium botulinum* toxin formation. Vacuum packed, refrigerated products must have a water phase salt level of 3.5% or higher to control

the food safety hazard of *Clostridium botulinum* toxin formation. If your firm begins manufacturing this type of product you must provide documentation that the process used consistently results in the desired water phase salt level.

3. Failure to monitor all relevant areas of plant sanitation, as required under 21 CFR Part 123.11(b). The areas of sanitation which are not monitored include:

   a. prevention of cross contamination;
   b. maintenance of hand washing, hand sanitizing, and toilet facilities;
   c. protection from adulterants;
   d. proper labeling, storage, and use of toxic compounds; and
   e. control of employees with adverse health conditions.

   Additionally, once your firm establishes sanitation monitoring procedures, you will need to maintain records of your sanitation monitoring and any corrections made as a result of that monitoring, as required under 21 CFR Part 123.11(c).

The above deficiencies were brought to your attention during the June 1998 inspection. These same issues were detailed in a letter from the FDA dated August 11, 1998. The FDA believes nine months is more than sufficient time to correct these deficiencies and we are gravely concerned that your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

Additional deficiencies noted during the inspection include:

1. Verification procedures were not listed in your HACCP plan. 21 CFR Part 123.6(c)(6) requires you to list verification procedures and frequency thereof, in your HACCP plan.

2. Your firm was checking and recording the temperature of the cooler once per day; however, the time the temperature check was made was not recorded as required under 21 CFR Part 123.9(a)(2).

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421.

Sincerely,

Del A Petterson for

Roger L. Lowell
District Director

Enclosures:
FORM FDA 483
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: With Disclosure Statement
WSDA