



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M28847

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDERAL EXPRESS

August 24, 1999

Our Reference: 2953914

Robert V. Morris, Owner
Morris Smoked Fish Company
780 Rockaway Beach Avenue
Pacifica, California 94044

WARNING LETTER

Dear Mr. Morris:

On February 22 and 25, 1999, Investigators Darla Bracy and Mark Nakano of the U.S. Food and Drug Administration (FDA) conducted an inspection of your seafood processing facility. The inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practice requirements for foods (21 CFR 110). The inspection detected deviations which constitute violations of the Federal Food, Drug, and Cosmetic Act (the Act), and related regulations for seafood processing and good manufacturing practices.

FDA analysis of a sample of cold-smoked salmon, collected during the inspection, revealed that the product contains *Listeria monocytogenes*. The lot of cold-smoked salmon is deemed adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act, in that it contains *Listeria monocytogenes*, a poisonous and deleterious substance which may render the food injurious to health. We acknowledge your firm's efforts to recall the tainted lot of smoked salmon although

nothing was recovered.

During the inspection, FDA also collected for analysis a sample of hot-smoked trout. Results of the analysis by the FDA laboratory showed that one of the ten subsamples of hot-smoked trout has a water phase salt of 2.65 percent and 2.54 percent by original and check analysis, respectively. To control *Clostridium botulinum* toxin formation in a vacuum packaged smoked fish or smoke-flavored fish, the guideline for water phase salt is 3.5 percent or higher. Water phase salt below 3.5 percent would not provide a preventive control for *C. botulinum* toxin formation in a refrigerated, vacuum packaged, smoked fish or smoke-flavored fish product. The sample test results demonstrate that your firm has not adequately established a process that will consistently provide a finished product of hot-smoked trout with the desired water phase salt (21 CFR 123.16).

At the conclusion of the inspection, the FDA investigators provided you with a copy of the Domestic Seafood HACCP Report (form FDA 3501) and the FDA 483 (Inspectional Observations) and discussed the findings with you. Briefly, these deviations are as follows:

1. Failure to list appropriate monitoring procedures in the HACCP plan for each of the critical control points (CCP) as required by 21 CFR 123.6(b) and (c)(4). Specifically, your plan lists the monitoring of water phase salt every two months at the brine step CCP. This monitoring would be more appropriate as a verification procedure. Your plan could state that brine strength is based on a recipe; however, you should record the time in brine for every batch in a daily log. The storage CCP for cold smoked salmon should state a temperature critical limit, e.g., 38°F, and this should be monitored by noting the temperature of the storage unit at least two times per day.
2. Failure to list in the HACCP plan an appropriate critical control point for a food safety hazard that is reasonably likely to occur as required by 21 CFR 123.6(b) and (c)(2). Specifically, for cold smoked salmon, the drying and smoking steps listed in the process schedule need to be listed as critical control points. Appropriate monitoring for such CCPs would be the recording of the time and temperature of the process for each batch, e.g., a temperature recording chart like the one used in hot smoking. In addition, finished product storage should be listed as a CCP for hot smoked trout as it is for cold smoked salmon.

3. Failure to maintain sanitation control records as required by 21 CFR 123.11(c) that document the monitoring and corrections of sanitary conditions and practices specified in 21 CFR 123.11(b) during processing.

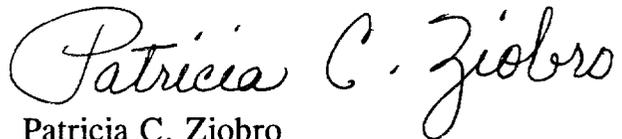
Vacuum packaged, cold-smoked salmon and hot-smoked trout processed in your facility under these conditions are adulterated within the meaning of Section 402(a)(4) of the Act in that they were prepared, packed, or held under insanitary conditions whereby they may be rendered injurious to health.

Adulterated foods are subject to seizure as authorized by Section 304 of the Act. Adulteration of food while held for sale after receipt in interstate commerce, is prohibited by Section 301(k). Section 302 authorizes the government to seek injunctive relief to restrain violations of Section 301 of the Act.

You must immediately take appropriate steps to correct the violations at your facility. Failure to correct the violations may result in legal sanctions such as seizure and/or injunction without further notice.

Please advise us in writing, within fifteen working days of receipt of this letter, the measures you have instituted to correct these violations, including an explanation of each step being taken to prevent recurrence of these violations. Please direct your response to Ms. Erlinda N. Figueroa, Compliance Officer (Telephone: 510-337-6795; FAX: 510-337-6707).

Sincerely,



Patricia C. Ziobro

Director

San Francisco District