DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
San Francisco District

1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 9, 1998

Our Reference: 2953218

Anders Holm, President
Scandinavian Smoke House, Inc.
250 Napoleon Street, Unit M
San Francisco, California 94124

WARNING LETTER

Dear Mr. Holm:

On July 29, 1998, FDA Investigator Mark Nakano 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 requriements for foods (21 CFR 110). The inspection documented deviations which constitute violations of the Federal Food, Drug and Cosmetic Act, and related regulations for seafood processing and good manufacturing practices.

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

1. Failure to have and implement a written HACCP plan for smoked sturgeon as required by 21 CFR 123.6(b).

2. Failure to have adequate control measures to address the food safety hazards associated with smoked sturgeon as required by 21 CFR 123.6(b). For example, your firm does not have

control measures established for the subsequent processing steps after the fish comes out of the smokehouse.

3. Failure to have an adequate written HACCP plan for smoked salmon as required by 21 CFR 123.6(b). Specifically, your firm failed to establish monitoring and verification procedures as required by 21 CFR 123.6(c)(4) and 21 CFR 123.8, for each of the processing steps, namely, brining, smoking, and finished product storage, where a food safety hazard was identified.

4. Failure to have and implement a written HACCP plan for smoked trout, shrimps, scallops, and mussels as required by 21 CFR 123.6(b).

5. Failure to maintain the relevant monitoring control records as required by 21 CFR 123.6(c)(7).

6. Failure to maintain the relevant sanitation control records as required by 21 CFR 123.11(c).

7. Poor employee practice of not sanitizing the stainless steel brine tank and the cutting boards for raw fish and for finished products.

Foods 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 become contaminated with filth, or 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).

Similar HACCP deviations were observed during the previous inspection on March 4 and 9, 1998. Following the March 1998 inspection, the FDA investigators presented a written list of inspectional observations and discussed the findings with you. These HACCP deviations were also reported to you by correspondence from this office on May 19, 1998. We are concerned that you have not corrected the HACCP deviations cited in our previous letter although you told the investigator that you would correct them. We acknowledge, however, that other sanitation violations had been corrected.

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 implemented 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,

Charles D Moss

Charles D. Moss
Acting District Director
San Francisco District