



U.S. Food and Drug Administration

New York District
850 Third Avenue, Brooklyn, New York 11232

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10/20/97
HF1-35

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

October 6, 1997

Emerich Tauber, Owner and Manager
Tauber's Smoked Fish
4529 16th Avenue
Brooklyn, NY 11204

re: 1-NYK-98

Dear Mr. Tauber:

During an inspection of your fish processing facility located at the above address conducted July 24 and 30, 1997 by our investigators and microbiologist, samples of in-process and processed fish products, and environmental swabs, were collected at your facility. At the conclusion of the inspection you were issued a Form FDA 483 (copy attached) which delineated insanitary conditions present in your facility at the time of the inspection. These conditions cause fish products manufactured in your facility to be adulterated under the Federal Food, Drug, and Cosmetic Act (the Act). Food that is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health, is adulterated within the meaning of section 402(a)(4) of the Act.

The following is a list of the insanitary conditions observed by our investigators during the inspection.

1. The floors and drainage facilities were deficient. For example, the floor drain was clogged in the packing/weighing room and the processing room, and standing water was present on the floor in those rooms and in the refrigerator. The floor of the processing room was broken, cracked, uneven, and pitted. Boxes of unprocessed whitefish were staged directly on the floor in the processing room and in the storage room, and those in the storage room were noted to have surfaces wet. Also, FDA analysis of the sample collected during the inspection detected Listeria monocytogenes Type 1 in a swab taken from the standing water on the floor in the processing room.
2. Poor practices were observed. Hand sanitation was not used by the employee while handling raw and finished products. Uncovered product was noted in the freezer and the refrigerator.

3. The equipment was not maintained appropriately. For example, the freezer and refrigerator thermometers were inoperable; in the processing room a hook implement and a floor squeegee were rusty and pitted and hooks used to hang fish in the ovens were stored with one end on the floor. The plastic entrance flaps covering the refrigerator doorway were encrusted with dried product residue or had missing sections.
4. General building maintenance was deficient. For example, ceilings and walls were noted peeling and in disrepair, or with pieces hanging or held up with wood, or encrusted with grease and product residue in the packing and weighing room, the refrigerator, and the processing room. Overhead light fixtures lacked protective covers over processing, electric wires were hanging from the light fixtures or the fan in the processing room. The skylight to the roof was leaking and water was dripping on the floor and onto the processing equipment in the storage room.

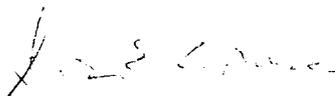
Neither this letter, nor the observations presented to you by the investigator or discussed with you during or at the conclusion of the inspection by our investigators are meant to be all-inclusive. It is your responsibility to assure that fish products are processed at your facility in compliance with the Federal Food, Drug, and Cosmetic Act.

You should take prompt action to correct the noted violations. Failure to promptly correct these deviations or other similar deviations of your products may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or intend to take to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the correction will be completed. Our investigator noted on the second day of the inspection that a repairman was present and repairs were being planned. Please let us know the status of repairs and your plans for repairs.

Your reply should be sent to the Food and Drug Administration, New York District Office, at the above address, Attention: William Friedrich, Compliance Officer.

Sincerely yours,



Alonza E. Cruse
Acting District Director
New York District