



DEPARTMENT OF HEALTH & HUMAN SERVICES

11-22597  
New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

December 11, 1998

**WARNING LETTER NYK 1999-12**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ronald Perelstein, President  
Schneider's Fish & Seafood Corp.  
2150 Old Union Road  
Cheektowaga, NY 14227

Dear Mr. Perelstein:

An inspection was performed at your fish processing facility on August 31, September 1, 4, and 8, 1998 by U.S. Food and Drug Administration (FDA) Investigator Joseph A. Famiglietti. The inspection covered two of your products, cooked lobster and fresh Mahi Mahi. Our findings reveal these products are adulterated within the meaning of Section 402(a)(4) of the Federal Food Drug, and Cosmetic Act. They were produced and held under conditions contrary to 21 CFR 123 which constitute insanitary conditions whereby they have been rendered injurious to health.

As explained in our previous Untitled Letter dated April 20, 1998, the seafood processing regulations, effective December 18, 1998, require your implementation of a preventative system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.

Our inspection revealed your processing of cooked lobsters deviates from regulations contained in 21 CFR 123 as follows:

- Failure to have and implement a written HACCP plan for whole cooked lobster to address food safety hazards that are reasonably likely to occur, 21 CFR 123.6(b).

Our inspection revealed your processing of the fresh histamine-forming species Mahi Mahi, deviates from regulations contained in 21 CFR 123 as follows:

Schneider's Fish & Seafood Corp.

Page 2

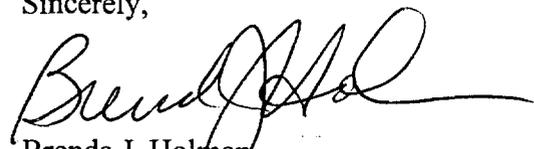
- Failure to list the procedures, and frequency thereof, that will be used to monitor the storage critical control point to ensure compliance with the critical limits, 21 CFR 123.6(c)(4).
- Failure to maintain sanitation control records in accordance with 21 CFR 123.11(c).
- Failure to maintain records documenting the monitoring of both the receiving and storage critical control points 21 CFR 123.6(c)(7). For example: review of records which document the monitoring of critical control points between 4/1/98 to the time of our inspection revealed, (1) On 6/19/98 no records were made to document internal temperatures taken on Fresh Tuna and Mahi Mahi upon their receipt, and (2) Failure to maintain records showing temperatures of vehicles used to transport incoming seafood and to maintain records showing cooler storage temperatures on nine dates between 5/5/98 and 8/11/98.

You should take prompt action to correct these and all violations at your firm. Failure to achieve corrective action may result in further regulatory action- without further notice. These actions include seizure and/or injunction.

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violation and prevent a reoccurrence of similar violations. Your response should be directed to William J. Thompson, Compliance Officer, at the above address.

Finally, to avoid any confusion on your part, you should have already received an earlier letter concerning our August 31 inspection. The letter concerns your handling of imported seafood, whereas the subject letter concerns your processing of seafood in the domestic trade.

Sincerely,



Brenda J. Holman  
District Director