



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

August 9, 2001

WARNING LETTER NYK 2001-112

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Ronald Perelstein, Owner  
Schneider's Fish & Seafood Corp.  
2150 Old Union Road  
Cheektowaga, New York 14227

Dear Mr. Perelstein:

We inspected your firm, located at 2150 Old Union Road, Cheektowaga, NY, on July 25-27, 2001 and found you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause your vacuum-packed Yellowfin Tuna to be in violation of section 402(a)(4) of the Federal Food, Drug and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

The deviations are as follows:

- You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for vacuum-packed Yellowfin Tuna to control the food safety hazard of Clostridium botulinum toxin formation.
- You must maintain a recordkeeping system that documents the monitoring of critical control points (CCPs), to comply with 123.6(b). However, your firm lacks monitoring records for the CCPs of thawing and labeling for vacuum packed Yellowfin Tuna.

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

Other deviations from the Seafood HACCP regulations, and from the requirements of 21 CFR Part 110, were also noted during the inspection, and should be corrected as soon as possible. These include the failure to maintain calibration records for thermometers used in the refrigerated cooler

Schneider's Fish & Seafood Corp.

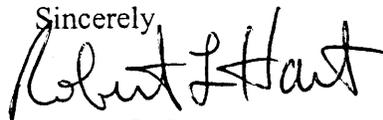
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where vacuum-packed products are stored [21 CFR 123.8(a)(2)(ii) and 123.8(a)(3)(iii)]; and failure to maintain adequate sanitation control records [21 CFR 123.11(c)].

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all enabling regulations.

Please notify this office in writing, within 15 days, of the specific steps you have taken to correct the noted violation and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Compliance Officer, at the above address. Mr. Kewley can be reached at (716) 551-4461, ext. 3128. You may wish to include documentation with your response, such as your HACCP plan for processing vacuum-packed Yellowfin Tuna, and examples of the associated process monitoring records.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert L. Hart". The signature is written in a cursive style with a large, prominent "R" and "H".

Robert L. Hart

Acting District Director