DEPARTMENT OF HEALTH AND HUMAN SERVICES 94995d

Food and Drug Administration
Minneapolis District Office
Central Region
212 Third Avenue South
Minneapolis, MN 55401
Telephone: (612) 334-4100
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September 23, 2004

**WARNING LETTER**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**Refer to MIN 04 - 36**

Bernard E. Gussel
President
Holiday Wholesale, Incorporated
225 Pioneer Drive, P.O. Box 177
Wisconsin Dells, Wisconsin 53965

Dear Mr. Gussel:

On May 20 and 21, 2004, we inspected your seafood processing facility located in Wisconsin Dells, Wisconsin. We found that you have serious deviations from the seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C § 342(a)(4). Accordingly, your ready-to-eat Tuna Salad, Pickled Herring, and Alaskan Crab Salad are adulterated in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulations through links in FDA's home page at *www.fda.gov.* You were previously informed of your obligations as a seafood processor in our letter to you of December 10, 1998.

The deviations of most concern are as follows:

1. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical

control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for ready-to-eat Tuna Salad and Pickled Herring lists a critical limit, "Max. Temp. [redacted] at the Receiving critical control point and "Max. Temp. [redacted] at the Storage critical control point that are not adequate to control pathogen growth and toxin formation. FDA recommends a critical limit of 40 °F or less. Histamine and/or toxin formation (produced by microbial growth) are hazards that can result from exposure to temperatures above 40 °F for extended periods of time.

2. You must have a HACCP plan that, at a minimum, lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for ready-to-eat Tuna Salad and Pickled Herring lists a monitoring frequency of twice daily at the Storage critical control point that is not adequate to control pathogen growth and toxin formation in your ready-to-eat products.

   Checking the temperature [redacted] daily leaves a gap of [redacted] hours between temperature checks. This is sufficient time for temperatures to fluctuate, rising sufficiently over an unmonitored and extended time period to allow for pathogen growth and toxin formation and also for dropping back down to a safe temperature before the next [redacted] hour check of the temperature. FDA recommends continuous time and temperature monitoring for coolers where ambient temperature is the sole source of cooling. One recommended method of monitoring is by a time/temperature data recorder.

3. You must implement the monitoring procedures that you have listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the incoming temperature monitoring procedure listed in your HACCP plan for ready-to-eat Tuna Salad and Pickled Herring for every shipment of product received to control pathogen growth and toxin formation. At least five shipping invoices lacked temperature values, and your firm's day warehouse supervisor stated that once the weather turned cold this past winter, the warehouse employees stopped taking receiving temperatures.

4. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). However, your corrective action plan for ready-to-eat Tuna Salad and Pickled Herring lists a corrective action, "Possibly Refuse Shipment" at the Receiving critical control point and "Repair Problem" and "Evaluate Product and Time" at the Storage critical control point that do not meet the requirements of 21 CFR 123.7(b)(1) and (2) to ensure that no adulterated product enters commerce and the cause of the deviation is corrected. FDA recommends that your listed corrective action plan at the Receiving critical

control point should list definitive criteria for determining when a lot will be refused.

At the conclusion of the inspection, our FDA investigator pointed out that your firm had a product, Alaskan Crab Salad, which was not listed on a seafood HACCP plan. As a processor of seafood, you must conduct a hazard analysis for each of your products to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control these food safety hazards to comply with 21 CFR 123.6(a) and (b). Since this product is packaged in a 4.5 lb. container, FDA considers it reasonably likely that the food safety hazard of *Clostridium botulinum* can occur. A hazard analysis of the product will determine whether you need to develop a HACCP plan or if this product could be added to an existing HACCP Plan because the hazards and critical control points are the same.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product and/or enjoin your firm from operating.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with our assessment of deviations from the seafood HACCP regulations, you should explain how your system identifies hazards and implements controls in a manner that the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and that there may be more than one right way to control hazards.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

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 Current 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 applicable regulations.
For information regarding recommended control strategies for pathogen growth and toxin formation, please refer to the *FDA Fish and Fishery Products Hazards*

*and Controls Guidance, Third Edition*, Chapter 12 (Pathogen Growth & Toxin Formation as a Result of Time/Temperature Abuse), found at *http://www.cfsan.fda.gov/~comm/haccp4.html*.

Please send your reply to the Food and Drug Administration, Attention: Tyra S. Wisecup, Compliance Officer, at the address in the letterhead. If you have questions regarding any issue in this letter, please contact Compliance Officer Wisecup at (612) 758-7114.

Sincerely,

W. Charles Becoat
Director
Minneapolis District

TSW/ccl