



VIA FEDERAL EXPRESS

Our Reference: 2921164

July 29, 2004

John H. Musser, Owner  
A-1 Sandwich Wholesale Co.  
429 Cabot Road  
South San Francisco, California 94080-4819

### WARNING LETTER

Dear Mr. Musser:

On March 29, 2004, and again on May 24, 2004, the U.S. Food and Drug Administration (FDA) conducted inspections of your facility at 429 Cabot Road, South San Francisco, California.

During the inspection, samples of tuna salad mixture and tuna salad sandwiches were collected and analyzed. Based on analytical findings of *Listeria monocytogenes*, a pathogenic microorganism, tuna salad mixture and tuna salad sandwiches represented by these samples are adulterated within the meaning of Section 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S. Code 342 (a)(1), in that they bear or contain a poisonous or deleterious substance which may render them injurious to health. *Listeria monocytogenes* is the causal organism of listeriosis, a disease most commonly associated with eating food contaminated with *Listeria monocytogenes*. Listeriosis can be very serious, even fatal for high-risk groups such as unborn babies, newborns, and those with impaired immune systems. The most serious forms of listeriosis can result in meningitis and septicemia. Pregnant women may contract flu-like symptoms, and complications can result in miscarriage, stillbirth, septicemia or meningitis in the newborn. In older children and adults, complications usually involve the central nervous system and bloodstream, but may include pneumonia and endocarditis.

Additionally, we found that you have serious deviations from the seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). These deviations cause your tuna sandwiches to be adulterated within the meaning of Section 402(a)(4) of the Act, in that the seafood products have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You can find the Act and the seafood HACCP regulations through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your serious HACCP deviations are as follows:

1. You must conduct or have conducted for you a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur, and 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(a) and (b). However, your firm does not have a HACCP plan for tuna sandwiches to control the food safety hazard of pathogen growth.
2. You must maintain sanitation control records that, at a minimum, document the monitoring and corrections prescribed by 21 CFR 123.11(b), to comply with 21 CFR 123.11(c). However, your firm does not maintain the following sanitation monitoring records, which are required for the preparation of tuna sandwiches to control the food safety hazard of pathogen growth:
  - Safety of the water
  - Condition and cleanliness of food-contact surfaces
  - Prevention of cross-contamination
  - Maintenance of hand washing, hand sanitizing, and toilet facilities
  - Protection of food, food packaging material, and food contact surfaces from adulteration with contaminants
  - Proper labeling, storage, and use of toxic compounds
  - Control of employee health conditions that could result in microbiological contamination, and
  - Exclusion of pests from the facility.

The above is not meant to be an all-inclusive list of violations at your facility. You are responsible for ensuring that your processing facility operates in compliance with the Act, the seafood HACCP regulations, and the current Good Manufacturing Practice regulations.

We may take further action if you do not correct the above violations. For instance, we may move to seize your products and/or enjoin your firm from operating.

Please notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the deviations. Your response should outline the specific things you have done and are doing to correct the above-listed deviations. You may wish to include in your response documentation that would assist us in evaluating your corrections. If you have not completed 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.

Your response should be directed to: Ms. Harumi Kishida, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Kishida at (510) 337-6824.

Sincerely,

A handwritten signature in black ink, appearing to read "Barbara J. Cassens". The signature is fluid and cursive, with the first name being the most prominent.

Barbara J. Cassens  
District Director  
San Francisco District