



August 27, 2001

WARNING LETTER NO. 2001-NOL-51

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. John W. Pierce, President and Owner
J & A Business, Inc.
d.b.a. Johnny & Alan's Sandwiches
2650 Old Brandon Road
Pearl, MS 39208

Dear Mr. Pierce:

We inspected your firm, located at 2650 Old Brandon Road, Pearl, Mississippi, on May 25, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123) and the Current Good Manufacturing Practice regulations, Title 21, *Code of Federal Regulations*, Part 110 (21 CFR 110). These deviations cause your tuna salad sandwiches to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, your Roast Beef and Cheese, Smoked Sausage, and Chili Dog sandwiches are misbranded under sections 403(a)(1) and 201(n) and 403(i)(2) of the Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at <http://www.fda.gov>.

The deviations were 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 tuna salad sandwiches to control the food safety hazard of pathogen growth and toxin formation.
- You must have sanitation control records that document monitoring and corrections in order to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for any of the following eight areas of sanitation: safety of 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; proper labeling, storage, and use of toxic compounds; control of employees with adverse health conditions; and, exclusion of pests.

In addition, the investigators documented numerous insanitary conditions that cause the sandwich products you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). They are adulterated because they have been prepared, packed or held under conditions whereby they may become contaminated with filth.

Employees working in direct contact with food and food contact surfaces did not take necessary precautions to protect against contamination of those items with microorganisms or foreign substances. For example, they did not wear adequate hair restraints during operations.

The Roast Beef and Cheese, Smoked Sausage and Chili Dog sandwiches are misbranded under Sections 403(a)(1) and 201(n) of the Act because the labels fail to reveal facts that are material to individuals who must avoid the following substances due to allergic reactions from their consumption. For example:

- (a) Roast Beef and Cheese sandwich contains wheat and soy protein;
- (b) Smoked Sausage sandwich contains corn flour and soy protein; and,
- (c) Chili Dog sandwich contains soy protein.

These sandwiches are also misbranded under Section 403(i)(2) of the Act because they contain ingredients, which themselves contain two or more ingredients not listed in the ingredient statement. These findings are further detailed in the enclosed Form FDA 483 that was discussed with you at the conclusion of the inspection.

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

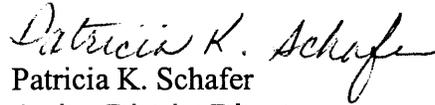
Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific actions you are taking to correct these deviations. You may wish to include in your response documentation such as your HACCP plan, sanitation monitoring records, and temperature monitoring records 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 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.

Page 3 - Mr. John W. Pierce, President and Owner/J & A Business, Inc., Pearl, Mississippi

Please send your reply to Mark W. Rivero, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Mr. Rivero at (504) 253-4519.

Sincerely,



Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: Form FDA 483

cc: Mr. Alan House, Co-Owner
J & A Business, Inc.
d.b.a. Johnny & Alan's Sandwiches
2650 Old Brandon Rd.
Pearl, Mississippi 39208