



May 20, 2002

WARNING LETTER NO. 2002-NOL-30

**FEDERAL EXPRESS
OVERNIGHT DELIVERY**

Mr. Daniel J. Bodin, President
Bodin Foods, Inc.
704 Avenue D
Acadiana Regional Airport
New Iberia, Louisiana 70560

Dear Mr. Bodin:

We inspected your firm, located at 704 Avenue D, New Iberia, Louisiana, on February 7 – 8, 2002, and found that you have serious deviations from seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123), and the Current Good Manufacturing Practice (CGMP) regulations in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations cause your seafood pies and seafood boudin to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must conduct, or have conducted for you, a hazard analysis to determine the food safety hazards that are reasonably likely to occur and have a HACCP plan that lists these food safety hazards to comply with 21 CFR 123.6(a) and 21 CFR 123.6(c)(1). However, your firm's HACCP plans for seafood pie and seafood boudin products do not list the food safety hazards of:
 - a. allergenic ingredients, particularly allergens such as wheat, soy, and nonfat milk;
 - b. pathogen growth/toxin formation; and,
 - c. undeclared sulfiting agents.
- You must have a HACCP plan that lists the critical limits that must be met to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plans for shrimp or crawfish pies, crawfish and crab meat pies, and shrimp and crab meat pies lists a critical limit of

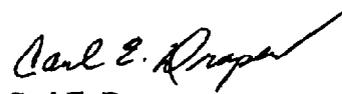
[REDACTED] at the cooling and freezing critical control point. This is not adequate to control the food safety hazard of pathogen growth and toxin formation. For example, if the product is held at an internal temperature above 70°F during processing, exposure time should ordinarily be limited to two hours (three hours if *Staphylococcus aureus* is the only pathogen of concern).

We may take action without further notice if you do not correct these violations promptly. For instance, we may seize your products and/or enjoin your firm from operating. We are aware that during our inspection you made a verbal commitment to correct violations observed at your firm. However, you must respond in writing, within three (3) weeks from your receipt of this letter, outlining specific actions you have taken to correct the deficiencies and to assure that such violations will not recur. You may wish to include in your response documentation such as your revised HACCP plans, 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 you will explain the reason for the delay and a deadline by which you will correct any remaining deficiencies.

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 CGMP regulations. You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

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

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483