



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration
Atlanta District Office**

g1436d

60 8th Street, N.E.
Atlanta, Georgia 30309

June 15, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rebecca McGinn, Owner/President
Little River Fish House, Inc.
P.O. Box 855
Little River, SC 29566

Warning Letter
01-ATL-48

Dear Mrs. McGinn:

On April 26 and May 5, 2001, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your plant located at 4492 Waterfront Drive, Little River, South Carolina. During that inspection, our investigator documented deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause your fresh, histamine-susceptible (scombroid) fish to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The HACCP deviation of concern is as follows:

You must have and implement 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 scombroid fish to control the food safety hazard of histamine formation. Our records show that our investigator had brought this deviation to your attention during FDA's January 1998 inspection of your plant.

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 things you are doing to correct these deviations. You may wish to include in your response documentation such as copies of HACCP plans, and HACCP 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 Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to Carlos A. Bonnin, Compliance Officer, U.S. Food and Drug Administration, 60 Eighth Street, N.E., Atlanta, Georgia 30309. If you have questions regarding any issue in this letter, please contact Mr. Bonnin at 404-253-1277.

Sincerely,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director 
Atlanta District