



March 28, 2001

WARNING LETTER NO. 2001-NOL-18

FEDERAL EXPRESS
OVERDRAFT DELIVERY

Mr. Michael A. Gangi, Sr.
Owner and President
Gangi Seafood, Inc.
600 Mazant Street
New Orleans, Louisiana 70117

Dear Mr. Gangi:

We inspected your firm, located at 600 Mazant Street, New Orleans, Louisiana, on March 16, 20, and 21, 2001, and found that you have serious deviations from Seafood Hazard Analysis Critical Control Point (HACCP) regulations, Title 21, *Code of Federal Regulations* (21 CFR), Part 123. These deviations, which were previously brought to your attention, cause your specialty seafood products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act). You can find this Act and the Seafood HACCP regulations through links in FDA's homepage at www.fda.gov.

During this inspection, the FDA investigator observed the following deficiency:

- 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). Your firm does not have a HACCP plan for shrimp addressing the control of the food safety hazard(s) of undeclared sulfites.

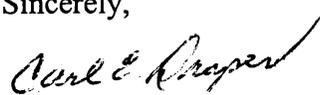
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

We are aware that at the close of the inspection you made a verbal commitment to correct the observed deficiencies. Please respond to this office in writing within three (3) weeks from 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: your HACCP plan for shrimp, copies of your sanitation monitoring records, copies of corrective action data, 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, within three (3) weeks from receipt of this letter, 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 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.

Please send your reply to Ms. Rebecca A. Asente, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Asente at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: FDA Form 483