



August 17, 2001

WARNING LETTER 2001-NOL-44

FEDERAL EXPRESS
OVERNIGHT DELIVERY

Mr. Jack Hines, President
Foods C'Est Bon, Limited
825 Oxley Street
Kenner, Louisiana 70062

Dear Mr. Hines:

A representative of the State of Louisiana, acting on behalf of the U.S. Food and Drug Administration (FDA), inspected your firm, located at 825 Oxley Street, Kenner, Louisiana on May 4, 2001, and found that you have serious deviations from the Seafood HACCP regulations, Title 21, *Code of Federal Regulations*, Part 123 (21 CFR 123). These deviations, some of which were previously brought to your attention, cause your seafood products to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- You must have a HACCP plan that lists the critical control points to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for bacon wrapped shrimp does not list the critical control point of labeling for controlling the food safety hazard of sulfiting agents. Your failure to address the control of sulfites in a shrimp product HACCP plan was previously brought to your attention in our untitled letter dated June 22, 1999.
- You must implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow your HACCP plan monitoring procedure that shrimp are not to exceed [REDACTED] during processing.
- You must retain all mandatory records for official review to comply with 21 CFR 123.9. However, your firm does not maintain records of official calibration of either the hand-held or the freezer/cooler entrance thermometers.

During the inspection, the Louisiana State inspector documented insanitary conditions that also cause the products you manufacture to be adulterated within the meaning of Section 402 (a)(4) of the Act as follows:

1. The inspector documented conditions which facilitate unsanitary operations, which are associated with unclean food contact surfaces. For example, mushrooms and celery were sliced on a table where beef had previously been processed.
2. The inspector documented conditions that facilitate unsanitary operations, which are associated with cross-contamination from insanitary objects to food. For example, during processing, employees wore watches, hanging earrings, and other jewelry.
3. The inspector documented conditions that facilitate unsanitary operations, which are associated with pests in the food plant. For example, your Operational Sanitation Report does not include monitoring of the exclusion of pests from the food plant. A fly was observed to land on your food product, and small insect droppings were present in a storage area.
4. The inspector documented a condition that facilitates unsanitary operations, which are associated with the lack of control of employee health conditions. For example, your Operational Sanitation Report does not include monitoring control of employee health conditions.

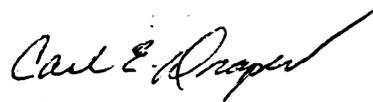
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

We are aware that you made a verbal commitment to correct the violations observed at your firm. However, you must 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 with your response documentation such as your corrected HACCP plan, thermometer calibrations, modified Operational Sanitation Report, 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 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 the Food and Drug Administration, Attention: Nicole F. Hardin, Compliance Officer at the above address. If you have questions regarding any issue in this letter, please contact Ms. Hardin at (504) 253-4519.

Sincerely,



Carl E. Draper
District Director
New Orleans District

Enclosure: FD 31