



August 27, 2001

WARNING LETTER NO. 2001-NOL-52

**FEDERAL EXPRESS
OVERDRAFT DELIVERY**

Mr. Brent C. Gutierrez, President
Custom Pack, Inc.
555 Bayview Avenue
Biloxi, Mississippi 39530

Dear Mr. Gutierrez:

We inspected your firm, located at 555 Bayview Avenue, Biloxi, Mississippi, during July 17-19, 2001, and found that you have serious deviations from the 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) in manufacturing, packing, or holding food for human consumption, 21 CFR 110. These deviations, which were previously brought to your attention, cause your specialty seafood products, including cooked IQF shrimp, bait shrimp and cooked, vacuum-packed, frozen shrimp rings and wedges, 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.

Our investigator provided you with a Form FDA 483 presenting his evaluation of your firm's compliance with applicable aspects of the HACCP requirements. Referring to the Form FDA 483 issued on July 19, 2001:

- 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 the processing of Bait Shrimp addressing the potential hazard of pathogen growth and toxin formation as a result of time and temperature abuse.

Your firm does not have a HACCP plan for the processing of cooked IQF salad shrimp addressing the potential hazard of pathogen growth and toxin formation as a result of time and temperature abuse or water sanitation and quality.

- You must have a HACCP plan that lists the food safety hazards that are reasonably likely to occur to comply with 21 CFR 123.6(c)(1). Your firm's HACCP plan for cooked, vacuum-packed, frozen shrimp rings and wedges does not list the food safety hazard of the potential hazard of *Clostridium botulinum* toxin formation.

Moreover, your firm's HACCP plan for cooked IQF shrimp does not list the food safety hazard of the potential hazard of pathogen growth due to time and temperature abuse during processing.

- You must have a HACCP plan that lists the critical control point to comply with 21 CFR 123.6(c)(2). However, your firm's HACCP plan for cooked, vacuum-packed, frozen shrimp rings and wedges does not list the critical control points of thawing, packing, and storage, for instance, for controlling the food safety hazards of potential pathogen growth and toxin formation.

In addition, your firm's HACCP plan for cooked, vacuum-packed, frozen shrimp rings and wedges does not list the critical control point of packaging, taking into account your use of permeable intact packaging film with an oxygen transmission rate of [REDACTED] and the controlling of the food safety hazard of the potential hazard of *Clostridium botulinum* toxin formation.

Our investigator also documented insanitary employee practices that can also cause the product you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act. At least six of your employees were observed, on July 18, 2001, returning from break directly to the processing work area without sanitizing their hands before handling raw shrimp.

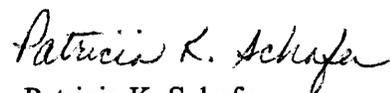
The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your processing plant is operating in compliance with applicable requirements and regulations. It is also your responsibility to assure not only that the current objectionable conditions are corrected, but that appropriate policies and procedures are implemented to prevent recurrence of the problems. Failure to make corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

We are aware that on July 19, 2001, our investigator discussed with you that on July 17, 2001, he noted cooked IQF salad shrimp, originally labeled as a product of Canada, being repackaged into finished product packages without the country of origin declaration present on the label. We are also aware that on July 19, 2001, you promised to correct the above listed HACCP regulation and labeling deviations.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific actions you are taking to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time by which the corrections will be completed.

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,



Patricia K. Schafer
Acting District Director
New Orleans District

Enclosure: FDA Form 483