



September 9, 2004

Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

WARNING LETTER
CHI-19-04

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Yu Hui Zheng, President
Golden Link, Inc.
443 North Williams St.
Thornton, IL 60476

Dear Mr. Zheng:

On April 22, 28, 30, and May 7 and 13, 2004, the Food and Drug Administration (FDA) and Illinois Department of Public Health (IDPH) conducted a joint inspection of your warehouse located at 443 N. Williams St., Thornton, Illinois, as a follow-up to a seafood HACCP report April 21, 2004, and IDPH inspection of March 2004. The inspection evaluated and discussed your compliance with the FDA Hazard Analysis Critical Control Point (HACCP) regulations. This joint inspection was made again, to evaluate HACCP requirements. At the conclusion of the inspection, you were presented with FDA-483, Inspectional Observations, and Form FD-3501, Domestic Seafood HACCP Report. The reports describe deviations from FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for Human Food (21 CFR 110). By virtue of these violations, the seafood products processed at your facility at 443 N. Williams St., Thornton, Illinois, are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, the investigators found the following seafood HACCP violations:

- **Failure to prepare and implement a HACCP plan to control a food safety hazard that is reasonably likely to occur.** You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and 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(a) and (b). However, your firm does not have a HACCP plan for shellfish including raw unfrozen oysters to control the food safety hazards of pathogens, natural toxins, or chemicals that you receive, store, and distribute.

The violations cited are not all inclusive. It is your responsibility to evaluate your program and ensure it is in compliance with the regulations. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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You should notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. Please include documents of the corrections such as your seafood HACCP plan, any documentation of calibration, etc., to prevent violations from recurring. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply relating to these concerns should be directed to the attention of Paul Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott J. MacIntire", with a long horizontal flourish extending to the right.

Scott J. MacIntire
District Director