



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

g/419d

June 18, 2001

WARNING LETTER  
CHI-36-01

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Timothy R. Young, President  
Dorina/So-Good, Inc.  
17400 E. Jefferson St.  
Union, IL 60180

Dear Mr. Young:

On April 23 and 24, 2001, an investigator with the Food and Drug Administration (FDA) conducted an inspection of your plant. The inspection was conducted to determine compliance with FDA's seafood processing regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123), and Good Manufacturing Practice (GMP) regulations for foods (21 CFR 110).

The inspection found that you have serious deviations from the Seafood HACCP regulations. These deviations, some of which were previously brought to your attention, cause your processed seafood products 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](http://www.fda.gov).

These serious deviations are as follows:

- You must implement the record keeping system listed in your HACCP plans, to comply with 21 CFR 123.6(b). However, your firm did not have or they were not made available, monitoring observations of critical limits for your shrimp gumbo and clam sauce/chowder cook processes.
- 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). However, your firm's HACCP plan for SHRIMP GUMBO does not list the hazard of sulfiting agents.

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.

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 (21 CFR Part 123) and the Good Manufacturing Practice regulations (21 CFR Part 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 respond in writing within three 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 updated HACCP plans, critical control points, critical limits, time/temperature monitoring records, product specifications for imported seafood products, with corrective action reports 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.

Please send your reply to the Food and Drug Administration, Attention Paul Boehmer, Compliance Officer at the Chicago District Office, 300 S. Riverside Plaza, Suite 550 South, Chicago, IL 60606. If you have questions regarding the implementation of the HACCP regulations or the application of HACCP to your specific process, you may contact Investigator Darrell Luedtke at the Gurnee Office for answers and/or direction toward guidance and sources of training in achieving compliance. His telephone number is (847) 249-8632, extension 28.

Sincerely,

\s\

Raymond V. Mlecko  
District Director