



June 21, 1999

WARNING LETTER
CHI-26-99

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

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William E. Dugan, President
Superior Ocean Produce
4423 N. Elston
Chicago, IL 60630

Dear Mr. Dugan:

On March 19 and 22, 1999, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to our previous inspection on May 8 and 13, 1998. At the conclusion of the inspection, you were presented with Form FDA-483, Notice of Observations, and Form FD-3501, Domestic Seafood HACCP Report describing 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 this facility are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our investigator found the following continued violations:

- Failure to prepare and implement a HACCP plan to control a food safety hazard that is reasonably likely to occur. Examples include Scombrotoxin formation in fresh tuna, mahi mahi, et al. and chemicals and drugs in aquacultured fresh Idaho trout.

The above conditions were issued previously in our letter to you dated July 2, 1998, in which you responded to the corrections made by letter of July 17, 1998. Those changes, which were substantial, did not correct the specific items addressed on the FDA 483, FDA 3501 or in our letter, in that you continue to lack written HACCP Plans or documentation for monitoring and corrective action of your sanitation procedures for your seafood products.

You should take prompt action to correct these violations. We are concerned that these serious violations continue since our inspection in May 1998. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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. 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. We are also providing firms the opportunity to take a HACCP refresher course to assist in better understanding and working with the Seafood HACCP program. Please contact the local FDA office for further information. If you enroll in one of these courses, we will consider extending your period for corrections or delaying further regulatory action provided products are not critically compromised resulting in a danger to health.

In addition to the above seafood HACCP processing deficiency, we also observed a continued failure to monitor and record sanitation practices and procedures or corrective action (Reference - 21 CFR Section 123.11 and Part 110). These violations included:

- Safety of the process water;
- Condition and cleanliness of food contact surfaces;
- Prevention of cross contamination;
- Maintenance of hand washing and hand sanitizing facilities;
- Protection from adulteration;
- Proper labeling, storage and use of toxic compounds;
- Control of employee health conditions; and
- Exclusion of pests.

Your reply relating to these concerns should be directed to the Food and Drug Administration, Attention: Paul Boehmer, Compliance Officer, at the Chicago District Office.

Sincerely,

/s/
Raymond V. Mlecko
District Director