



November 23, 1998

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

WARNING LETTER

CHI-6-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Kazuya Tanaka, President
Tanaka, Inc., d.b.a. Big Tuna
1900 N. Austin
Chicago, IL 60639

Dear Mr. Tanaka:

On August 4 and 5, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant as a follow-up to our previous inspections of March 4, 5 and 6, 1998, and June 4 and 5, 1998. At the conclusion of the inspection, you were presented with Form FDA 483, Notice of Observations, and Form FDA 3501, Domestic Seafood HACCP Report describing deviations to 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 deficiencies, the fresh tuna processed at your facility is 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 have and implement a HACCP plan to control a food safety hazard that is reasonably likely to occur (Scombrotoxin formation in fresh tuna). Reference – 21 CFR 123.6
- Failure to document the monitoring of critical control points for the receiving, storage, and processing of fresh tuna. Reference – 21 CFR 123.6(b)
- Failure to monitor and record sanitation practices and procedures (Reference – 21 CFR 123.11 and Part 110). The required monitoring and record keeping includes:
 - 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; and
 - Control of employee health conditions.

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You should take prompt action to correct these violations. We are concerned that no real improvements or corrections were made since our inspections in March and June 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.

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

Sincerely,

/s/
Raymond V. Mlecko
District Director