



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

New England District

g1270d

One Montvale Avenue
Stoneham, Massachusetts 02180
Tel 781.279.1675
Fax 781.279.1742

May 4, 2001

WARNING LETTER

NWE-21-01W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Philip (Fei) Pan, President
Oriental Food Marketing, Inc.
305 Main Street
Everett, MA 02149

Dear Mr. Pan:

We inspected your firm, located at 305 Main Street in Everett, MA on April 2, 3, 6, and 9, 2001, and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations, some of which were previously brought to your attention, cause products being processed by your firm—salmon maki, tuna maki, and salmon nigiri—to be in violation of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

- ▶ 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). The document you provided to our investigator does not specifically address the food safety hazards of pathogen growth and histamine formation. It lacks mandatory features, such as Critical Control Points, Critical Limits, and Monitoring Procedures.
- ▶ You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). No sanitation monitoring was observed during our inspection. In addition, your firm does not maintain sanitation control records, which

are a requirement under 21 CFR § 123.11(c). Sanitation controls are particularly important for ensuring the safety of ready-to-eat product (i.e., items that are intended to be consumed without further cooking).

These observations have been previously reported to you in a letter from this office dated May 15, 2000 (SH-15-00 NWE). There is no record in our files of a response to that letter.

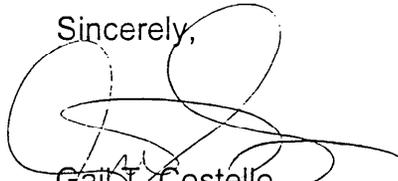
We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your 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 a completed HACCP plan and sanitation monitoring records, 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.

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 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 send your reply to the Food and Drug Administration, Attention: Mark Lookabaugh, Compliance Officer, 1 Montvale Avenue, Stoneham, Massachusetts 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.279.1675 x1718**

Sincerely,



Gail Costello
Director
New England District