



DEPARTMENT OF HEALTH & HUMAN SERVICES  
Food and Drug Administration  
New England District

94258

One Montvale Avenue  
Stoneham, Massachusetts 02180  
Telephone: 781.596.7700  
Facsimile: 781.596.7899

August 13 2003

**WARNING LETTER**

**NWE-24-03W**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Eddie Lai, Owner  
Sake Sushi USA  
305 Main Street  
Everett, MA 02149

Dear Mr. Lai:

Between June 18 and 25, 2003, the Food and Drug Administration (FDA) inspected your seafood processing facility, located at 305 Main Street, Everett, MA. We found that you have a serious deviation from the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123 (21 C.F.R. Part 123). In accordance with 21 C.F.R. § 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your ready-to-eat California maki, shrimp maki, and shrimp nigiri are adulterated, in that these fishery products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov).

Your deviation was as follows:

- ▶ 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 C.F.R. §§ 123.6(a) and (b). However, your firm does not have a HACCP plan (or plans) for California maki, shrimp maki, and shrimp nigiri to control the food safety hazards of pathogen growth during processing and allergens during finished product labeling

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

Please respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as a HACCP plan (or plans) for your firm's sushi products and copies of associated monitoring records, or any 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 regulation, and the Good Manufacturing Practice regulation (21 C.F.R. 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, MA 02180. If you have questions regarding any issue in this letter, please contact Mr. Lookabaugh at **781.596.7751**.

Sincerely,



Gail T. Costello  
Director

New England District