



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

November 16, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Shultz A. Hartgrove III, President
Sushi Ready
5140 Race Court #7
Denver, Colorado 80216

Dear Mr. Hartgrove:

We inspected your firm, located at the above address, on July 11-23, 2001 and found that you have serious deviations from the Seafood HACCP regulations [Title 21 Code of Federal Regulations, Part 21 (21 CFR Part 123)]. We regret the delay in writing this letter to you. The deviations we found cause your fresh and vacuum packed fish products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find 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). However, at the time of the inspection, your firm has not conducted a hazard analysis, and did not have a HACCP plan for your shrimp spring roll.

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 sushi product, which contains raw tuna, does not list histamine as a hazard.

You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21 CFR 123.6(c)(4). However, your firm's HACCP plan for sushi lists a monitoring procedure at the cooler storage critical control point of "At least twice daily" that is not adequate to control pathogen and/or histamine growth.

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You must fully document, in records, all corrective actions taken, to comply with 21 CFR 123.7(d). However, you did not document at a corrective action was taken when you deviated from your critical limit of maximum cooler temperatures for sushi at the cooler storage critical control point to control pathogen and/or histamine growth.

You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedures of Cooler Log monitoring records nor time and temperature of rice batches at the cooler temperature and processing critical control points, respectively, to control pathogen and or histamine growth listed in your HACCP plan for sushi products.

You must correct sanitation deficiencies detected during monitoring in a timely manner, to comply with 21 CFR 123.11(b). However, you firm did not correct the sanitation deficiencies of:

Condition and cleanliness of food contact surfaces, including utensils, gloves, and outer garments is not adequate, as required by 21 CFR 123.11(b)(2). For example, we noted trays and tubs stacked nested on top of each other, and not allowed to air dry; and using a rusty vegetable peeler to peel cucumbers and carrots.

Prevention of cross contamination from insanitary objects to food and other food contact surfaces, including utensils, gloves, and outer garments is not adequate, as required by 21 CFR 123.11(b)(3). For example, we noted the returning of peeled vegetables into the same tote which held the unpeeled, unwashed vegetables; the dropping of two clean sushi boats onto the floor, and the return of them to the clean utensil rack without cleaning and sanitizing; and knives used to open boxes, then used to cut sushi without cleaning and sanitizing.

Protection of food and food contact surfaces from adulteration with cleaning compounds and sanitizing agents is not adequate, as required by 21 CFR 123.11(b)(5). For example, the large metal bowl used to mix imitation crabmeat contained a pool of sanitizer, soap, and water. This mixture was not washed out, but wiped with a towel prior to use. Also, sanitizer used on processing tables is not allowed to air dry or otherwise removed prior to using the tables to process sushi.

In addition, we found your processing did not allow food to remain at a cool enough temperature to minimize the potential of the growth of pathogens, which would render the food adulterated within the meaning of section 402(a)(3) of the Act. For example, rice noodles cooked the night previously and stored overnight in a walk in cooler were found to be ~~at~~ at 6:40 am, and ~~at~~ at 8:06 am. Pathogens can grow in this type of product at temperatures over 45°F. In addition, the temperature of a spicy tuna

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mixture was found to be \times . The remainder of this batch was mixed in with a new batch with a temperature of 40°F before mixing. This may cause the tuna mixture to become adulterated under section 402(a)(3) of the Act, in that histamine can develop at temperatures above 40°F.

We may take further action if you do not promptly correct these violations. For instance, we may 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 and the Good Manufacturing Practice regulations (21 CFR 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 (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 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 direct your response to the Food and Drug Administration, Attention: Ms. Shelly L. Maifarth, Compliance Officer, at the above address. If you have questions regarding any issue in this letter, please contact Ms. Maifarth at (303) 236-3046.

Sincerely,


Thomas A. Allison
District Director

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