



DEPARTMENT OF HEALTH AND HUMAN SERVICES

M 3296 n
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

December 22, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-24

Henderson Mar, President
Entrees, Inc.
800 Maynard Avenue South, Suite 101
Seattle, Washington 98134

WARNING LETTER

Dear Mr. Mar:

We inspected your firm, located at 800 Maynard Avenue South, Seattle, Washington, on August 18, 1999, and found that you have serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery products (Seafood HACCP Regulations). These deviations, some of which were previously brought to your attention, cause your frozen and refrigerated sushi products to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find this Act and the Seafood HACCP regulations through links in the Food and Drug Administration's (FDA) home page at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazard that is reasonably likely to occur, in order to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for frozen and refrigerated ready-to-eat sushi products to control the food safety hazard of pathogen growth. This deviation was previously brought to your attention in our letter of April 12, 1999.
2. You must adequately monitor sanitation conditions and practices during processing, in order to comply with 21 CFR 123.11(b). However, your firm did not monitor seven of eight areas of sanitation including:
 - a. Safety of process water
 - b. Conditions and cleanliness of contact surfaces
 - c. Prevention of cross contamination
 - d. Maintenance of hand washing, hand sanitizing, and toilet facilities
 - e. Protection from adulterants

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- f. Proper labeling, storage, and use of toxic compounds; and
- g. Control of employee health conditions.

This deviation was previously brought to your attention in our letter of April 12, 1999.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product 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 your revised HACCP plan and copies of your 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 Act and all applicable regulations. Pertinent sections of the Act and regulations are enclosed for your review.

Please send your reply to the Food and Drug Administration, Attention: Robert L. Wesley, Compliance Officer, 1000 2nd Avenue, Suite 2400, Seattle, Washington 98104. If you have any questions regarding any issue in this letter, please contact Mr. Wesley at 206/553-7001, extension 57.

Sincerely



Kristy D. Thies
Acting District Director

Enclosures:
21 CFR Part 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: WSDA With Disclosure Statement