

March 7, 2003

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 03-14
Kai Wakabayashi, Owner
Sonny Foods
6069 B. Hannegan Road
Bellingham, Washington 98226

WARNING LETTER

Dear Mr. Wakabayashi:

We inspected your firm located at 6069 B. Hannegan Road, Bellingham, Washington, on September 16-17, 2002, 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). A FDA 483 form (copy enclosed) listing the deviations was presented to you at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your smoked salmon jerky 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 FDA's homepage at www.fda.gov.

The deviations are as follows:

1. You must have a HACCP plan that lists monitoring procedures for each critical control point, to comply with 21-CFR 123.6(c)(4). Your firm's HACCP plan for smoked vacuum packaged salmon jerky lists a monitoring frequency of "once per batch" at the "Cooking/Drying/Smoking" critical control point that is not adequate. FDA currently suggests that monitoring be continuous, with a visual check of the monitoring instrument (your temperature recorder) at least once per batch at the "Cooking/Drying/Smoking" critical control point to control the hazard of pathogen growth and toxin formation.
2. Since you chose to include corrective actions in your HACCP plan, your described corrective actions must be appropriate, to comply with 21 CFR 123.7(b). Your corrective action plan for smoked jerky at the slicing and cooking/drying/smoking critical control points to control pathogen growth are not appropriate.

Corrective action plans must include steps to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation and the cause of the deviation is corrected.

3. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). Your firm did not monitor proper labeling, storage, and use of toxic compounds an exclusion of pests from the food plant with sufficient frequency to ensure control for each day of processing. Based on your records, monitoring for these areas of sanitation was done on [REDACTED] basis rather than on a daily basis between July 6, 2001 to September 13, 2002. Exposure to toxic compounds (e.g., detergents and sanitizers) and exclusion of pests is normally associated with daily processing. As evidenced of the need for more frequent monitoring, our investigator documented more than 35 flies in the processing area.
4. You must maintain sanitation control records that, at a minimum, document monitoring and corrections to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation monitoring records for safety of water, conditions and cleanliness of food contact surfaces, prevention of cross contamination from insanitary objects, maintenance of hand washing, sanitizing and toilet facilities, protection of food and food packaging materials from chemical contaminants, proper labeling and storage of toxic compounds, control of employee health conditions, and exclusion of pests from the food plant for the following dates: April 15-19, 2002; May 6-10, 2002; May 13-17, 2002, May 20-25, 2002, June 10-15, 2002; and August.

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.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) 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.

Wakabayashi, Owner
Foods, Bellingham, WA
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Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021. If you have questions regarding any issue in this letter, please contact CO Elrand at (425) 483-4913, or email her at lelrand@ora.fda.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", with a long horizontal flourish extending to the right.

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: WSDA with disclosure statement