



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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

March 19, 2001

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 01-36  
Myong Bracy, Owner  
Portland Sandwich Company  
4181 South East Division Street  
Portland, Oregon 97024

WARNING LETTER

Dear Ms. Bracy:

We inspected your firm located at 4181 South East Division Street, Portland, Oregon, on January 25, 2001, 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 Jeff S. Mallett, Manager, at the conclusion of the inspection. These deviations, some of which were previously brought to your attention, cause your tuna and cheese sandwich 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 FDA's homepage at [www.fda.gov](http://www.fda.gov).

The deviations of concern were as follows:

1. 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). Your firm does not have a HACCP plan for tuna and cheese sandwich products to control the food safety hazard of allergens at the labeling step and pathogen survival during the refrigerated storage step for your process. These same violations were brought to your attention during our last inspection on March 7, 2000, and in a letter to you from the FDA dated March 30, 2000.
2. You must have sanitation control records that document monitoring and corrections, to comply with 21 CFR 123.11(c). Your firm did not maintain sanitation control records for all eight areas of sanitation. This violation has also been ongoing since your last inspection and documented in the March 30, 2000 letter to you.

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You could not provide our investigator with monitoring records for the following eight areas of sanitation:

- a. Safety of water;
- b. Condition and cleanliness of food contact surfaces;
- c. Prevention of cross-contamination;
- d. Maintenance of hand washing, hand sanitizing, and toilet facilities;
- e. Protection from adulterants;
- f. Proper labeling, storage, and use of toxic compounds;
- g. Control of employees with adverse health conditions; and
- h. Control of pests.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA, including the Seafood HACCP regulations and the Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food regulations in 21 CFR 110. 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. Pertinent sections of the Act and regulations are enclosed for your review.

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.

For your information, our investigator observed personnel in the processing area without the presence of hairnets, aprons, and other processing attire. In accordance with 21 CFR 110.10(b)(1) and 110.10(b)(6), all persons working in direct contact with food shall conform to the wearing of outer garments suitable to the operation in a manner that protects against contamination of that food.

In addition, upon review of your label for tuna and cheese sandwich products, our investigator noticed that your firm did not list the sub ingredients for your enriched bread. In accordance with 21 CFR 101.4(b)(2) an ingredient which itself contains two or more ingredients shall be designated in the statement of ingredients on the label by either a parenthetical listing of the sub ingredients of that component or incorporating each ingredient into a statement of ingredients in descending order of predominance in the finished food.

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Please send your reply to the Food and Drug Administration, Attention: Diane J. Englund,  
Compliance Officer, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421.

If you have any questions regarding any issue in this letter, please contact Diane J. Englund at  
(425) 483-4864.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen". The signature is fluid and cursive, with a long horizontal stroke at the end.

Charles M. Breen  
District Director

Enclosures:  
Form FDA 483  
21 CFR Parts 101.4, 110.10, 123.6, and 123.11  
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: OSDA with Disclosure Statement