



DEPARTMENT OF HEALTH AND HUMAN SERVICES

g1693d
Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

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

August 28, 2001

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 01-82
Anthony W. Moss, Owner
Inland Vending Expand O Systems, LLC
2107 Commerce
Boise, Idaho 83705

WARNING LETTER

Dear Mr. Moss:

We inspected your firm located at 2107 Commerce, Boise, Idaho, on July 17-18, 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 you, some of which were previously brought to your attention, cause your tuna fish sandwiches 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 deviation is 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 your tuna fish sandwiches to control the food safety hazard of histamine formation.
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 the eight areas of sanitation which are as follows:
 - Safety of water
 - Condition and cleanliness of food contact surfaces
 - Prevention of cross contamination
 - Maintenance of hand washing, hand sanitizing, and toilet facilities
 - Protection of food from adulterants
 - Proper labeling, storage, and use of toxic compounds

Anthony W. Moss, Owner
Inland Vending Expand O Systems, LLC, Boise, ID
Re: Warning Letter SEA 01-82
Page 2

- Control of employees health conditions
 - Exclusion of pests
3. The label for the products listed below do not list the sub-ingredients of ingredients such as milk, cheese, graham crumbs, whipped topping, mayonnaise, bread, and pudding, in order to comply with 21 CFR 101.4(b)(2). Any ingredients which itself contains two or more ingredients and has an established common or usual name, shall be designated in the statements of ingredients on the label of such food. One way to comply is to declare the common name of the ingredient followed by a parenthetical listing of its ingredients in descending order of predominance.
- Tuna Salad sandwich
 - Egg Salad sandwich
 - Chicken Salad sandwich
 - Ham Salad sandwich
 - Roast Beef and Cheese Sandwich
 - Meat Ball sandwich
 - BBQ Beef
 - Chocolate Chip Pudding Pie
 - Vanilla Oreo Pudding Pie
 - Banana Cream Pudding Pie
 - Coconut Cream Pudding Pie
 - Blueberry Cheese Cake
 - Cherry Cheese Cake

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.

Anthony W. Moss, Owner
Inland Vending Expand O Systems, LLC, Boise, ID
Re: Warning Letter SEA 01-82
Page 3

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 Lisa Elrand at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read "Charles M. Breen", written in a cursive style.

Charles M. Breen
District Director

Enclosures:
Form FDA 483

cc: ISDH with disclosure statement