



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

November 14, 2001

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-09

Mr. Gerald H. Bittner, President
Alaska Commercial Company
550 West 64th Avenue, Suite 200
Anchorage, AK 99518

WARNING LETTER

Dear Mr. Bittner:

The Food and Drug Administration (FDA) conducted an inspection of your warehouse located at 550 West 64th Avenue, Suite 200, Anchorage, Alaska, on August 22, and 23, 2001. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110 Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. At the conclusion of the inspection, Alaska Commercial Company President/COO, was issued a Form FDA-483 (copy enclosed) which delineated a number of gross insanitary conditions present in your warehouse at the time of the inspection. These conditions cause the food products stored in your warehouse to be adulterated within the meaning of Section 402(a)(4), (copy enclosed) of the Federal Food, Drug, and Cosmetic Act (the Act), in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth. You can find this Act through links in FDA's homepage at

The following is a list of the insanitary conditions observed by our investigators during the inspection:

1. Effective measures are not being taken to protect against the contamination of food on the premises by pests, in accordance with 21 CFR 110.35. Specifically, our investigator observed:
 - a. Rodent excreta pellets were observed on the floor level throughout the food storage areas of the warehouse and the refrigerated storage cooler. Evidence of rodents and rodent gnawed products and packaging was observed in the dog food, cat food, Danish Orchard Jam, and Top Ramen storage areas.

- b. On three separate occasions in three different areas of the food storage warehouse, rodents were observed running between pallets of stored food. One rodent in a spring trap and one dried carcass were observed in two separate areas along the west wall of the food storage warehouse.
 - c. Evidence of rodent gnawed and eaten product was observed on individual packages in cases of Top Ramen, specifically, nine cases of Cajun Chicken; four cases of Picante Beef, three cases of Chicken Mushroom; and one case of Chicken Sesame.
 - d. An estimated average of one hundred (100) rodent excrement pellets per linear foot were observed along the inside of the south and west perimeter walls.
 - e. An estimated average of twenty (20) rodent excrement pellets per linear foot were found along the outside perimeter of the refrigerated/frozen storage area.
2. Your firm failed to maintain buildings and physical facilities in sufficient repair to prevent food from becoming adulterated in accordance with 21 CFR 110.20, was also observed during the inspection by our investigator:
- a. The floor/wall juncture around the south and west walls of the food storage area of the warehouse has many holes that allow rodent access and harborage areas within the walls and along the edge of the floor. Dirt and sand was found dug out around many of these access holes. Around two of the access holes on the west wall, fiberglass insulation was found dug out from the wall.
 - b. The floor door jambs along the west wall of the food storage area have gaps, with at least one that would allow easy outside rodent access to the interior of the warehouse.
 - c. The floor/wall juncture of the refrigerated and frozen storage areas is not tightly sealed and has approximately a one and a half inch (1 ½ inch) gap that has allowed rodents easy access to the styrofoam insulated walls as a harborage area inside the warehouse. At least two gallons of styrofoam pellets from the insulating panels were observed on the floor in the gap between the refrigerated storage wall and the warehouse wall.
 - d. A one to two inch gap exists at the juncture of the south and west interior walls of the food storage area in which reps and rodent harborage were observed within the insulated walls.
 - e. Your firm did not adequately clean up product spills from torn or punctured bags of food products allowing the spilled product to serve as attractants to rodents.

Mr. Gerald H. Bittner ident
Alaska Commercial Company
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Our inspection has revealed that you have a serious rodent infestation problem in your warehouse. During our inspection you admitted that you were embarrassed to know that there is an active rodent infestation in the warehouse and you indicated that you will be taking action and making repairs to rid the warehouse of rodents. It is your responsibility to have an effective, ongoing sanitation program that eliminates the insanitary conditions we have observed.

The above violations are not meant to be an all-inclusive list of deficiencies in your facility. 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. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

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. 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 send your reply to the Food and Drug Administration, Attention: Connie P. Rezendes, Acting Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Connie Rezendes, Acting Compliance Officer at (425) 402-3178 or via e-mail at crezende@ora.fda.gov.

Sincerely,



Charles M. Breen
District Director

Enclosures:

Form FDA 483 -8/23/01

21 CFR PART 110

Section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act

cc: ADEC with disclosure statement