



March 12, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 99-10

Marianne DeWolf, President  
Butte Produce Company  
605 Utah Avenue  
Butte, Montana 59701

Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive S.E.  
P.O. Box 3012  
Bothell, WA 98041-3012

Telephone: 425-486-8788  
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WARNING LETTER

Dear Ms. DeWolf:

On February 5 and 8, 1999, the United States Food and Drug Administration (FDA) conducted an inspection of your firm located at 605 Utah Avenue, Butte, Montana. The inspection was conducted to evaluate your firm's compliance with good manufacturing practice requirements for foods, Title 21 of the Code of Federal Regulations, Part 110. At the conclusion of the inspection our investigator issued you a Form FDA 483 (copy attached) which delineated a number of gross insanitary conditions present in your firm at the time of the inspection. These conditions cause the products stored at your firm to be adulterated within the meaning of Sections 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

The following is a list of insanitary conditions observed by our investigator during the inspection.

1. Examination of flour products stored inside the dry storage warehouse (identified as the incoming goods warehouse) found rodent activity associated with at least nine different lots of bagged flour products and one lot of bagged brown sugar product. The types of rodent activity found by our investigator included:

- a. rodent excreta pellets in product;
- b. bags of product with rodent chewed holes;
- c. rodent excreta pellets on bags of product;
- d. rodent urine stains on bags of product;
- e. a large number of rodent pellets and rodent trails through flour spillage;
- f. dead mice in flour spillage;
- g. a large number of rodent excreta pellets on the pallet boards holding the bags of product; and
- h. a large number of rodent excreta pellets on the floor in the immediate vicinity of product.

Our investigator collected samples from the above-described lots and our laboratory analyses of those samples confirmed his observations.

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2. Rodent excreta pellets were found along the floor-wall junctures and on pallet boards in both the dry goods storage warehouse and the incoming goods storage warehouse.
3. Gaps up to one inch in height were found along the underside of closed loading doors. A loading door leading into the warehouse was left open during the day. Open loading doors and gaps along the underside of loading doors provide access for insects and rodents.
4. Several poor warehousing practices were noted, including the following:
  - a. Products inside bags were exposed due to torn and rodent chewed bags that were improperly repaired or covered.
  - b. Paper packaged products were not stored in a manner to preclude vermin access.
  - c. Products were stored against walls.
  - d. Canned and bagged products were left for long periods of time in warehouse storage.
  - e. Employees were smoking in the warehouse.
5. There were no hand washing or sanitizing facilities available to employees working in the vegetable repackaging area. Employees used their bare hands to remove vegetables from their original containers and place them into other containers for custom orders. The practice of handling non-food contact surfaces and then handling ready-to-eat vegetables without cleaning and sanitizing hands is an example of cross contamination that can lead to the contamination of products with pathogens (illness causing organism).
6. Hazardous materials, including [REDACTED] brand rodenticide, charcoal lighter fluid, odor guard, [REDACTED] brand antifreeze, and a grease gun were stored on an open shelf directly above the tomato/banana repackaging room, directly over exposed tomatoes.
7. Fluorescent lights inside the warehouse areas, including over the vegetable repackaging station, lacked protective shields, exposing stored and in-process products to non-shatter proof lights.
8. The established morgue areas in the dry storage, cooler, and freezer storage areas did not effectively separate product designated for shipping from damaged or returned products. Though you had designated morgue areas for damaged and returned goods, our investigator found acceptable food products stored in the immediate vicinity of, as well as intermixed with, damaged and returned goods.
9. Refrigerated trucks used to deliver produce and other food products to customers were not clean and miscellaneous debris was found on the floor of the vehicles inspected.

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You admitted to our investigator that you have an ongoing problem with rodent activity. Although you have contracted with a pest control company, it is clear that action alone has not resolved your rodent problem. This inspection, coupled with your firm's inspectional history, demonstrates to the FDA that you have an ongoing problem with rodent activity. It appears that your firm needs more aggressive pest control. The FDA acknowledges that you voluntarily destroyed the lots of products that were contaminated with rodent filth. However, we remain concerned that if our inspection had not revealed the extensive rodent activity and product contamination, the products would have been distributed and consumed.

It is your responsibility to assure 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.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Janelle K. Main, Compliance Officer, P.O. Box 3012, Bothell, Washington 98041-3012.

Sincerely,



Roger L. Lowell  
District Director

Enclosures:  
Form FDA 483  
Section 402 of the Act  
21 CFR Part 110

cc: With Disclosure Statement  
MSDH