



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
Central Region
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Cincinnati, OH 45237-3097
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VIA FEDERAL EXPRESS

February 4, 2004

Donald W. Greenwell, Owner
Greenwell Farms
345 Popcorn Road
Morganfield, KY 42437-6638

WARNING LETTER CIN-04-20418

Dear Mr. Greenwell:

On December 1-3 and December 16, 2003, the Food and Drug Administration (FDA) conducted an inspection of your popcorn manufacturing facility located at 345 Popcorn Road, Morganfield, KY. The inspection revealed numerous deviations from the Good Manufacturing Practice (GMP) regulations, Title 21, Code of Federal Regulations (21 CFR) Part 110. At the conclusion of the inspection, the Consumer Safety Officer and Analyst issued a Form FDA-483, Inspectional Observations which listed a number of gross insanitary conditions present in the facility at the time of the inspection. These conditions cause the food products manufactured and stored in your facility to be adulterated within the meaning of Section 402(a)(4) 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.

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

Effective measures are not being taken to protect against the contamination of food on the premises by pests, in violation of 21 CFR 110.35(c). Specific examples include:

- Two dead mice were found on the east side of the warehouse by the overhead doors.
- Approximately five dead roaches and roach egg cases were found along the walls and on boxes next to the food production area.
- Roach frass too numerous to count were found on boxes next to the stored sugar located in the east storage area.

Failure to maintain buildings in repair sufficient to prevent food from becoming adulterated in violation of 21 CFR 110.35(a). Examples include:

- An approximate 4" diameter hole in the corrugated plastic-type material serving as a window on the north side of the plant.
- An approximate 2" diameter hole in the wall on the north side of the building. The hole was at ground level.

Failure to take proper precautions to protect food and food-contact surfaces from contamination with filth due to deficiencies in plant design in violation of 21 CFR 110.20(b) (2). For example:

- A large vat containing corn syrup, water and brown sugar which is used to coat popcorn was not covered to protect against contamination from foot traffic up the adjacent stairs. The stairs are located inches from the vat.

Failure to construct the plant in such a manner as to take proper precautions to prevent condensate from contaminating food and food-contact surfaces in violation of 21 CFR 110.20(b) (4). For example:

- Condensate accumulated on the outside and under the mixing kettle after it was heated. The condensate was seen dripping onto the conveyor belt which transported the mixed popcorn to the cooling table.

Failure to locate fans and other air-blowing equipment in a manner that minimizes the potential for contamination of food and food-contact surfaces and failure to provide adequate ventilation to minimize odors and vapors in violation of 21 CFR 110.20(b)(6). For example:

- A dust covered fan was blowing air across a dusty surface onto finished popcorn product as it came from the conveyor belt, down the trough and onto the cooling table.
- The venting system to one of the popcorn machines was disconnected from the outside vent allowing exhaust from popcorn production to flow back into the production area.

Failure to confine the use of tobacco to areas other than where food may be exposed and equipment or utensils are washed in violation of 21 CFR 110.10(b) (8). For example:

- Approximately 25 cigarette butts were found scattered on the floor of the warehouse/production area. An ashtray containing cigarette butts and ashes and two packs of cigarettes were seen in the production area.

Failure to maintain toilet facilities in a sanitary condition in violation of 21 CFR 110.37(d) (1). For example:

- The men's restroom opened directly into the popcorn production/processing area. There was a large machine and gas can in the restroom. The men's restroom did not have hand drying equipment or paper towels. Neither the men's nor the women's restrooms had self closing doors or signs reminding employees to wash their hands.

Failure to provide sufficient space for placement of equipment and storage of materials as necessary for the maintenance of sanitary operations and the production of safe food in violation of 21 CFR 110.20(b) (1). For example:

- An accumulation of paper products, packaging supplies and boxes was located on the roof of the office area and exposed to the production/processing area of the plant.

Failure to properly store equipment, remove litter and waste, and cut weeds or grass that may constitute an attractant, breeding place, or harborage area for pests, within the immediate vicinity of the plant buildings or structures in violation of 21 CFR 110.20(a)(1). Specifically:

- The grounds in the back of the building (north side) were overgrown with weeds and tall grass which abutted up to the building.
- Pallets, machinery, plastic buckets and other debris were found adjacent to the building.

- Storage areas on the east and west side of the processing areas were found to contain a variety of junk items, raw materials, office equipment, production equipment, tools and paper products.

Failure to store raw materials in a manner that protects against contamination in violation of 21 CFR 110.80(a) (1). For example:

- Two bags of sugar, one bag of popcorn and one bucket of popcorn were left open and exposed to possible contamination.
- There were approximately five bags of opened finished popcorn and two cans of exposed unpopped popcorn were stored in a hallway off the production area.

Failure to dispose of rubbish in a manner that minimizes the potential for waste becoming an attractant and harborage or breeding place for pests in violation of 21 CFR 110.37(f). Specifically:

- Approximately ten boxes/bags of trash consisting of unusable popcorn, packaging materials and other trash were found throughout the manufacturing area.

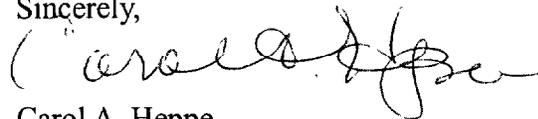
You should take prompt action to correct these deviations. Failure to do so may result in regulatory action, including seizure and/or injunction, being initiated by the FDA without further notice.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your facility operates in compliance with the Act and the Good Manufacturing Practice regulations, 21 CFR Part 110. You are responsible for implementing procedures to prevent further violations of the Act and all applicable regulations.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent recurrence. Your response should outline the specific things that you are doing to correct these deviations. You should include in your response documentation and written verification procedures 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.

Your reply should be sent to the Food and Drug Administration, Attention Stephen J. Rabe, Compliance Officer, 6751 Steger Drive, Cincinnati, OH 45237. If you have questions regarding this letter please contact Mr. Rabe at 513-679-2700, extension 164.

Sincerely,



Carol A. Heppe
District Director