



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Cincinnati District Office
6751 Steger Dr.
Cincinnati, OH 45237

VIA FEDERAL EXPRESS

June 18, 2003

Michael S. Embrescia, Co-Owner
Richard E. D'Ambrosia, Co-Owner
Variety Food Service, L.L.C.
3812 E. 91st Street
Cleveland, OH 44105

WARNING LETTER CIN-03-17748

Dear Mr. Embrescia and Mr. D'Ambrosia:

On April 28 – May 7, 2003, the Food and Drug Administration (FDA) conducted an inspection of your firm located in Cleveland, OH. The inspection revealed significant deviations from FDA's Current Good Manufacturing Practice requirements for foods, Title 21, Code of Federal Regulations (CFR), Part 110. Most of these deviations have been brought to your attention previously following an FDA inspection on April 10 & 11, 2003, and an Ohio Department of Agriculture inspection conducted on February 18, 2003, under FDA contract. These deviations cause your bakery products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 342(a)(4)), because they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

The observations of concern to us are as follows:

1. Dead rodents were observed throughout your facility, including the first floor processing area, the second floor processing area, and the warehouse [21 CFR § 110.35(c)].
2. Rodent pellets were observed throughout the facility, including both processing areas on the first and second floors [21 CFR § 110.35(c)].
3. Live insects were observed on one lot of peanuts and inside the proofing machine [21 CFR § 110.35(c)].
4. Failure to maintain your facility in sufficient repair to maintain sanitary conditions [21 CFR § 110.35(a)].
 - There are gaps around the doors and pipes leading to an attached abandoned warehouse. The abandoned warehouse has holes in the roof, walls, and windows with direct access to the outside.
 - Gaps around the dock doors.

- The roof over the second floor processing area was observed leaking in 27 different places.

5. Exposed rodent bait was observed throughout your facility, including both processing areas [21 CFR § 110.35(c)].

Our other concern is that your firm did not implement adequate corrective actions following the Ohio Department of Agriculture inspection conducted on February 18, 2003, and the FDA inspection conducted on April 10 & 11, 2003, even though corrections were promised during the inspections.

We acknowledge receipt of your firm's response dated May 15, 2003. However, your response does not adequately address your firm's long-term plan to ensure that a rodent and/or insect problem does not recur. Specifically:

1. You state that the dough mixer and proofer have been cleaned. Is this a one-time event or will this equipment be cleaned on a routine basis?
2. You state that you have placed 60 new rodent traps throughout your facility. However, you do not indicate who will monitor the traps or how often they will be monitored.
3. You state that you will install rodent bait stations along the outside perimeter of the building. Again, you do not state who will monitor the stations or how often they will be monitored.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your firm operates in compliance with the Act and the Current Good Manufacturing Practice regulations (21 CFR Part 110). We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure and/or injunction without further notice.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the violations. For corrections that you cannot complete within fifteen (15) working days, state the reason for the delay and your timeframe for completion. We also ask that you provide documentation of the corrections as they are made and that you explain your plan for preventing these violations in the future

Your reply should be sent to the Food and Drug Administration, Attention: Karen Gale Sego, Compliance Officer, 6751 Steger Dr., Cincinnati, OH 45237. If you have questions regarding this letter, please contact Karen Gale Sego, Compliance Officer, at (513) 679-2700, extension 164.

Sincerely,



Carol A. Heppe
District Director