



Telephone (973) 526-6004

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

January 6, 2003

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Joseph Falcone, President
Capital Foods, Inc.
1701 E. Elizabeth Avenue
Linden, New Jersey 07036

FILE NO.: 03-NWJ- 03

Dear Mr. Falcone:

On November 19 – 26, 2002, the U.S. Food and Drug Administration conducted an inspection of your facility located at 1701 E. Elizabeth Avenue, Linden, New Jersey. During the inspection our investigators documented serious violations of the Food, Drug, and Cosmetic Act (the Act) with respect to your failure to comply with Current Good Manufacturing Practice ("CGMP") in Manufacturing, Packing, or Holding Human Food, Title 21, Code of Federal Regulations, Part 110. The observed violations pertain to the production, holding, and distribution of your ricotta cheese products.

The inspection revealed that the food products manufactured at your facility are adulterated within the meaning of Section 402(a)(4) of the Act in that they are prepared, processed, and held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health. The deviations were presented to you on a FDA-483, List of Inspectional Observations, at the close of the inspection on November 26, 2002. The serious violations are as follows:

1. Gross rodent activity was noted in your facility. For example:
 - a. Six live adult mice were observed on pallets of Polly-O dry whey (50 lb.) bags and approximately 15 baby mice were found in a gnawed bag of dry whey.
 - b. Three live mice were observed on the food racks in the storage area.
 - c. One dead mouse was observed in the storage area.

- d. An examination of 14 bags of Polly-O dry whey (50 lb.) revealed evidence that rodents had chewed into the product in 10 bags, 3 bags were urine stained, 2 had rodent pellets on the bags, and 2 had rodent nesting material resting on the bags.
2. Doors that contain gaps and holes in the walls that provide access to the plant from the outside were noted. For example:
 - a. The bay door on the south side of the building, which provides access to the food storage area (where rodent activity was observed), had a gap approximately 3 inches high and 6 inches wide.
 - b. The bay door in the loading area does not close tightly to the ground, which results in a 1 inch gap and a hole in the right corner of the door.
 - c. The door on the east side of the building has a 1 inch gap between the bottom of the door and the floor.
 - d. Numerous holes in the plant walls were noted throughout the facility.
3. Failure to manufacture and store food products under conditions necessary to minimize the growth of microorganisms. For example:
 - a. Stagnant water was accumulating in the food storage area, below pallets of raw materials.
 - b. Mold growth was observed on the walls, ceiling, and vents in the production room, cooling room, and in the walk-in refrigerator, where finished product is stored.
 - c. The floor in the production area was peeling. The grout around the tiles in the production room was worn away and water was accumulating between the tiles.
 - d. Vents above the vats that are used to process ricotta cheese, had accumulation of condensation.
 - e. The ceiling in the production area was buckling.

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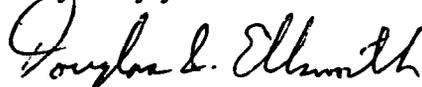
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Additionally, during our inspection investigators addressed compliance issues concerning the labeling of your ricotta cheese product. You must list all ingredients on the product label and/or labeling before you distribute your product. We are attaching a copy of the Food Labeling Guide. We acknowledge that you took corrective action during the inspection on November 21, 2002, by voluntarily destroying 82 bags of rodent adulterated Polly-O Dry Whey (50 lb.). However, this action did not address all of the compliance issues observed during the inspection and noted above. Therefore, we recommend you conduct a comprehensive evaluation of your facility to determine CGMP compliance.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Current Good Manufacturing Practice Regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This includes seizure and/or injunction.

You should notify this office in writing within 15 working days of receipt of this letter, of any additional corrective actions, including an explanation of each step being taken to prevent the recurrence of similar conditions. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which corrections will be completed. Your reply should be sent to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd, 3rd Floor, Parsippany, New Jersey 07054, Attention: Andrew Ciaccia, Compliance Officer.

Very truly yours,



Douglas I. Ellsworth
District Director
New Jersey District Office

AC:slm