



M5127

January 30, 2001

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

WARNING LETTER

CHI-9-01

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Brian A. Boomsma, President
Dutch Farms
700 East 107th Street
Chicago, IL 60628

Dear Mr. Boomsma:

On August 25 and 29, 2000, the U.S. Food & Drug Administration (FDA) inspected a firm for which you are off-site president, namely [REDACTED]. [REDACTED]. The inspection documented numerous insanitary conditions of the food-storage warehouse. The inspection was conducted at the request of the U.S. Department of Agriculture, Food Sanitation and Inspection Service (FSIS), following their reported finding of extensive rodent activity at this location, which stores meat, poultry and FDA-regulated products. This letter refers to our findings concerning FDA-regulated products only.

The insanitary conditions observed at your firm during our inspection cause your products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), because they have been held under conditions whereby they may have become contaminated with filth. Specifically, the inspection disclosed the following insanitary conditions:

- Rodent activity, in the form of rat excreta pellets, was observed on the roof of the first-floor interior office, in the third floor near packaging materials, and near a pallet of peppers in brine on the third floor.
- A rodent-gnawed bag of pancake mix and rodent-gnawed margarine packages, all on the second floor, demonstrated penetration to, and potentially direct contamination of, product inside.
- A structural hole in the surface of the third floor (opening into the ceiling of the second floor), and another hole in a basement wall (near a pallet of cheese), have provided potential avenues of entrance/egress of rodents.
- A cat was noted running among stored food items on the second floor.

- Cat feces were observed in the basement next to a pallet of cheese, and on a staircase between the second and third floors.
- In your firm's rear courtyard, rat burrow holes (including one at the base of your building), a dead rodent, several flies, containers with rotten eggs, over-filled trash dumpsters, unused manufacturing equipment, unidentified debris, and plant overgrowth were observed.

Other objectionable conditions observed during our inspection included cheese and other perishable items refrigerated at ■ degrees F, and various products stored directly against walls in the basement and on the first, second and third floors.

At the close of the inspection, your warehouse manager, Mr. Zachary S. Banner, was issued an FDA 483 (Inspectional Observations) listing deficiencies observed during the inspection. (A copy of the FDA 483 is enclosed.) Mr. Banner reported and we observed corrections to deficiencies that were contained in our list. Among others, corrections included voluntary destruction of various foods that were potentially contaminated by rodents. Your corrections also included necessary structural repairs and implementing a standard sanitation operating procedure (SSOP).

We acknowledge these corrective actions, and encourage you to continue such activities as needed to preclude products stored in your firm from becoming adulterated. For example, your SSOP plan, which currently identifies a walk-through inspection, pallet rotation and shelf cleaning, might also include specific procedures for a pallet/container surface and interstitial carton examination (on a regular basis), for rat, cat, insect and other pest activity. You may also want to accompany your pest control operator, to ensure his reports are always properly annotated, and that you are getting sufficient feedback on conditions that exist at your firm.

The above does not represent an all-inclusive listing of the violations noted during the inspection of your firm. It is your responsibility to assure adherence with each requirement of the Act and its regulations, and to be vigilant that products received, stored, and distributed in interstate commerce meet the requirements of the Act. Failure to maintain these requirements may result in regulatory action without further notice. These include seizure and/or injunction.

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Please notify this office in writing within 30 working days after receipt of this letter of any further corrections you have taken, or comments you wish to make, concerning these violations. Your reply should be directed to the attention of James Karpus, Compliance Officer, at the Chicago District Office.

Sincerely,

\s\
Raymond V. Mlecko
District Director