



DEPARTMENT OF HEALTH AND HUMAN SERVICES *SP*

Public Health Service
Food and Drug Administration *m3121n*

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*11/1/99
No purging*

HFI-35

September 30, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Marlin J. Klein
President
New York Bagelry
11375 Hammack Drive
Bridgeton, Missouri 63044

Re: STL-99-07

Dear Mr. Klein:

During an inspection of your bakery located at 11375 Hammack Drive, Bridgeton, Missouri, conducted on August 18-30, 1999, our investigators documented deviations from the Good Manufacturing Practices (GMP) Regulations (Title 21, Code of Federal Regulations, Part 110). These deviations cause your bakery product to be adulterated within the meaning of Section 402(a)(3) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

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

1. Live insects were observed in the bakery in the following areas:
 - a. 61 live beetle and larval type insects in the production area;
 - b. 35 live beetle and larval type insects in the ingredient storage warehouse;
 - c. 7 live beetle type insects in the packaging area; and
 - d. 1 live roach type insect in the ingredient storage warehouse.
2. Employee practices during bakery good production on 8/19/1999 were observed:
 - a. Employees not wearing hair and/or beard protection.
 - b. Bakery good ingredient residue on surfaces of equipment being used.
 - c. Unscreened overhead door was open when not in immediate use.

Our investigators collected 11 samples of raw ingredients from the production area. The FDA Kansas City Laboratory analysis of these samples (copies included) has confirmed the investigator's observations. For example:

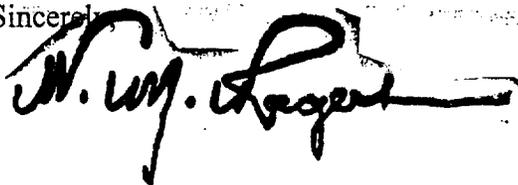
1. 65 Dermestidae Beetle/larvae, 25 Dermestidae Larvae cast skins, and 9 Saw-toothed Grain Beetle in white flour;
2. 8 Saw-toothed Grain Beetle/Larvae in pound cake mix;
3. 10 Dermestidae Larvae cast skins, 4 Dermestidae Larvae, and 3 Saw-toothed Grain Beetle in fine potato flour;
4. 27 Saw-toothed Grain Beetle, 30 Dermestidae Larvae, and 10 Cucujidae Larvae in whole grain bread mix;
5. 16 Saw-toothed Grain Beetle, Cucujidae, 6 Dermestidae Beetle in pound cake mix;
6. 1 Cigarette Beetle in white rye;
7. 1 Confused Flour Beetle in ground caraway;
8. 1 Confused Flour Beetle in chopped dried onion;
9. 1 Cigarette Beetle, 9 Confused Flour Beetle, and 8 Pribolium Larvae in whole wheat flour;
10. 4 Saw-toothed Grain Beetle and 9 Confused Flour Beetle in pumpernickle; and
11. 2 Confused Flour Beetle in sugar.

This letter is not intended to be all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA-483, Inspectional Observations, which is a list of the investigator's observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in immediate regulatory action without further notice. Such actions include product seizure and injunction.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrections will be completed. Your response should be sent to Andrew H. Paeng, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
Director
Kansas City District

Enclosure: Sample analysis reports