



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M2511

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

April 12, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Warren E. Schaller, President
Schaller's Bakery, Inc.
826 Highland Street
Greensburg, Pennsylvania 15601

Dear Mr. Schaller:

During an inspection of your bakery, located at the above address, on March 9, 1999, our investigator documented serious deviations from the Good Manufacturing Practices (GMP's) as listed in Title 21, Code of Federal Regulations, Part 110 (21 CFR § 110). At the conclusion of this inspection Wayne E. Schaller, Secretary/Treasurer Schaller's Bakery, was issued an FDA-483, Inspectional Observations (attached), and, these observations were discussed with him. These deviations cause the bakery products manufactured in your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act, in that,

Live Broad Horned flour beetles were observed and collected from multiple locations inside your flour handling system. Additionally, live insects were collected at the end of your flour conveyance system as flour was being fed into the mixer for preparation into bread dough.

Also, several general housekeeping deficiencies were observed.

The above violations are not intended to be an all-inclusive list of deficiencies at your bakery. As top management it is your responsibility to maintain your facility in a clean, sanitary condition so that foods made and stored there do not become unfit for human consumption. You should take prompt action to correct the violations described above. Failure to do so may result in regulatory action without further notice. Such action includes seizure and/or injunction.

We acknowledge receipt of your March 19, 1999, letter which proposes corrective actions to the findings noted in the above mentioned Form FDA-483 issued March 9, 1999; however, in view of the extent of the infestation in your flour handling system, we are asking that you notify this office in writing within (15) working days of receipt of this letter of all specific actions that have been implemented to correct the noted violations. This should include verification of the training of personnel and an explanation with verification of each step being taken to prevent recurrence

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of similar violations. If corrective action cannot be completed within (15) working days, state the reason for delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Philadelphia District Office, Room 900, U. S. Customhouse, 2nd and Chestnut Streets, Philadelphia, PA 19106, to the attention of William J. Forman, Compliance Officer.

Sincerely,


#7 Thomas D. Gardine
District Director
Philadelphia District

Attachment: FDA-483, Inspectional Observations, dtd. 3/9/99.

cc: Pennsylvania Department of Agriculture
John Stella, Regional Director
5349 William Flynn Highway
Gibsonia, Pennsylvania 15044