



DEPARTMENT OF HEALTH AND HUMAN SERVICES

HFI-35

1129507

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-30977
Telephone: (513) 679-2700
FAX: (513) 679-2761

September 14, 1999

WARNING LETTER
CIN-WL-99-139

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Ethyl M. Osman, President
Osman's Pies
4974 Darrow Road
Stow, Ohio 44224

Dear Ms. Osman:

On January 20, 22, 26, and 27, 1999, the Food and Drug Administration conducted an inspection of your pie manufacturing facility. The Establishment Inspection Report of this inspection reveals violations, which caused your pies to be deemed adulterated under 21 USC 342(a)(4). The product is misbranded under 21 USC 343(f) in that it fails to present the required ingredient statement on the label in terms which render it likely to be understood by the ordinary individual under customary conditions of purchase. The pies are misbranded within the meaning of 343(i)(2) of the Act in that:

- The label declares "certified FD&C color" in the list of fruit ingredients but fails to declare the "certified FD&C color" by specific common or usual name.
- Several ingredients are fabricated from 2 or more ingredients but the label fails to declare each sub-ingredient in the food by its common or usual name.

Further the pie labels are considered to be misbranded in that they fail to bear nutrition labeling as required by 21 USC 343(q)(1) and 21 CFR 101.9 and are not exempt under 21 USC 343(q)(5) from this requirement and have been labeled on or after May 8, 1994.

Some of these current conditions were observed during the Ohio Department of Agriculture's October 24, 1995, inspection. Promises to make correction were made to the State during the previous inspection.

You should take prompt action to correct these label deficiencies. Failure to promptly correct these label deficiencies may result in regulatory action being initiated by FDA without further notice. These include seizure and injunction.

"Our investigation further revealed several insanitary practices at your facility which could lead to contamination of the finished product with potentially harmful pathogens:

1. Employees leaving the work area and returning without washing their hands.
2. Employees drinking coffee, or other beverages, in the food processing areas.
3. Equipment washed and placed wet, for drying, on a worktable soiled with remnants of previous production. Soiled equipment was placed on the same table next to clean equipment.
4. Paint on the pie shell-rolling machine was peeling in a manner that the peeled paint could become incorporated into a piecrust.
5. Unused pie filling was stored in uncovered containers on the floor of the walk-in cooler.

Please notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason and the time within which the correction will be completed.

Your reply should be sent to the Food and Drug Administration at the above address, to the attention of Leonard J. Farr, Compliance Officer.

Sincerely yours,


Henry L. Fielden
District Director

LJF/llw