

M 3168N



DEPARTMENT OF HEALTH & HUMAN SERVICES

EB 11/19/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905
Telephone: (913) 752-2100

November 19, 1999

WARNING LETTER

Michael A. Barreca, Co-Owner
Barreca's, Inc.
921 Lydia
Kansas City, MO 64106

KAN #2000-005

Dear Mr. Barreca:

An inspection of your food manufacturing facility was conducted on June 23 through July 10, 1999, by Food and Drug Administration Investigators from this office. The inspection determined you manufacture an acidified food product, namely pickled bell peppers. In addition you manufacture a cannoli shell pastry product. This inspection found that pickled peppers are processed under serious deviations from Title 21, Code of Federal Regulations (21 CFR), Parts 108 and 114. The cannoli shells are manufactured under significant insanitary conditions. These deviations cause these products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act).

Deviations to 21 CFR Parts 108 and 114 include, but are not limited to the following:

- Your firm did not file scheduled processes for the pickled bell peppers that you manufacture as required by 21 CFR 108.25(c)(2).
- Your firm did not have a supervisor who has satisfactorily completed an approved course of instruction in the processing and packaging of acidified foods as required by 21 CFR 108.25(f).
- Your firm did not have a qualified processing authority verify the adequacy of your canning process as required by 21 CFR 114.83.
- Your firm did not monitor and record finished product equilibrium pH; and did not code individual product containers as required by 21 CFR 114.80; and did not maintain batch production records as required by 21 CFR 114.100.

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Barreca's, Inc.

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or issuance of an order of need for a Temporary Emergency Permit.

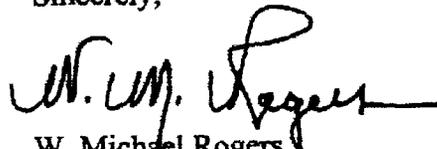
Other conditions noted during the inspection include:

- Various chemicals being stored near food products.
- Improperly cleaned raw product as noted by an adhesive produce sticker on a canned bell pepper.
- Evidence of eating, drinking and smoking in the food production area.
- No toilet paper or paper towels in the employee's restroom.
- Structural defects to include cracks in walls, non-working toilet and hand washing station, peeling paint, and poorly screened entry doors.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. Any corrective action taken should apply to all acidified products you manufacture. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,



W. Michael Rogers
District Director
Kansas City District