



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Refer to: 1117807

Food and Drug Administration
Baltimore District Office
Central Region
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2307

October 3, 2000

WARNING LETTER**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Mr. David T. Garber, President
Garber Ice Cream Company
P.O. Box 3265
360 Front Royal Pike
Winchester, Virginia 22602

Dear Mr. Garber:

The Food and Drug Administration (FDA) conducted an inspection of your ice cream manufacturing facility located in Winchester, Virginia on September 12, 2000. Our inspection revealed insanitary conditions in the manufacturing of ice cream in violation of the Food, Drug and Cosmetic Act (FD&C Act). Specifically, the ice cream products are adulterated within the meaning of Section 402(a)(4) of the FD&C Act, in that they are being produced under insanitary conditions that may render them injurious to health.

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

- A hose previously in contact with the floor and standing water and subject to foot traffic was observed being used by employees to spray food contact surfaces.
- A single flexible hose was used rather than permanently piped connections to pump ice cream into the two [REDACTED]. The unused [REDACTED] connection was left open while the second tank connection was in use.
- [REDACTED] cup fillers lacked any overhead covering or protection to exclude possible introduction of contaminants or foreign objects.
- Equipment was not designed or maintained in a manner to facilitate adequate cleaning. For example, flexible hoses have non-removable stub ends, creating possible point sources of contamination.
- The boiler make-up water storage tank and hose stations failed to have backflow prevention devices.

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- Employees were observed cleaning product spills on food contact surfaces using only paper towels without sanitizing the surface prior to resuming production.
- In excess of 100 apparent rodent and/or insect excreta pellets were observed along the east wall of the carton storage warehouse.
- Overgrown vegetation, old construction materials, and obsolete equipment were observed on the exterior of the firm, affording harborage and breeding areas for vermin.

The deficiencies noted above are not intended to be an all-inclusive list of violations at your facility. It is your responsibility to ensure compliance with all applicable laws and regulations.

You should take prompt action to correct the deviations noted above. Failure to do so may result in regulatory action being taken without further notice. This may include seizure and/or injunction.

Please notify us in writing, within 15 working days of receipt of this letter, of the corrections that you plan to implement. Your reply should be sent to the Food and Drug Administration, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046-4200, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller may be reached at 703-235-8440, Extension 504.

Sincerely,



Lee Bowers
District Director