



**DEPARTMENT OF HEALTH AND HUMAN SERVICE**

Public Health Service

Refer to: FEI 3002922756

g/269d  
Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-3396  
FAX: (410) 962-2219

01-BLT-028

May 1, 2001

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ms. Paula K. Kingry, Owner  
Dark Hollow Foods  
120 Taylor Road  
Dunbar, West Virginia 25064

Dear Ms. Kingry:

The Food and Drug Administration (FDA) conducted an inspection of your Acidified Low-Acid Food processing plant on April 12 and 19, 2001. At the conclusion of the inspection you were presented with a Form FDA-483 listing serious deviations from Title 21, Code of Federal Regulations (21 CFR), Part 114, Acidified Foods. 21 CFR Part 114 includes the Current Good Manufacturing Practice regulations for acidified foods. By virtue of these deficiencies, the products processed at your facility are adulterated within the meaning of section 402(a)(4) of the Food, Drug and Cosmetic Act (the Act).

Specifically, our investigator found that:

1. You have not assured that instruments and controls used for measuring the pH are accurate and adequately maintained. For example, you failed to calibrate the pH meter prior to each days use for the period between October 24, 2000 and April 12, 2001. [21 CFR 114.80(a)(2) and 114.90(a)(4)].
2. You have not assured that tests and examinations of your containers were conducted and documented to assure that the container protects food from leakage or contamination. For example, you failed to conduct or document glass jar seal integrity testing (Pull-Up Test) on each lot produced. [21 CFR 114.80(a)(4) and 114.100(b)].

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This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Inspectional Observations (Form FDA 483), issued to you during the inspection may be symptomatic of serious underlying problems in your firm's manufacturing processes and controls. You are responsible for investigating and determining the causes of the violations identified by the FDA, and promptly initiating permanent corrective actions. Also, other Federal agencies are advised of the issuance of all Warning Letters so they may take this information into account when considering the award of contracts or issuing certificates of export.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

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 and to prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,



Lee Bowers  
Director, Baltimore District

cc: Mr. Ronald K. Forren, Director  
WV DHHR/Bureau for Public Health  
Office of Environmental Health Services  
815 Quarrier St., Suite 418  
Charleston, WV 25301-2616