



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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Food and Drug Administration  
Nashville District Office  
297 Plus Park Blvd.  
Nashville, TN 37217

June 30, 1999

*Quigley*  
6/30/99  
JEA

**CERTIFIED - RETURN RECEIPT REQUESTED**

Mr. Robert K. Anders, President  
Holston Gases, Inc.  
222 Council Place  
Knoxville, TN 37927

**Warning Letter - 99-NSV-17**

During an inspection of your oxygen gas repacking facility located at 1306 Lebanon Road, Nashville, Tennessee on June 9 and 11, 1999 our investigators documented deviations from the Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act.

The inspection revealed a failure to document and follow your Standard Operating Procedure (SOP) with the nitrogen standard in calibration of your ~~nitrogen standard~~. Our inspection also found a failure to perform all of the required SOP tests on filled oxygen units, incomplete batch records, and a failure to show that a responsible individual of your firm had reviewed and signed your written procedures.

The above identification of violations is not intended to be an all-inclusive list of deficiencies. It is your responsibility to ensure adherence to each requirement of the Good Manufacturing Practice Regulations. Until the violations are corrected, federal agencies will be informed that FDA recommends against the award of contracts for the affected products.

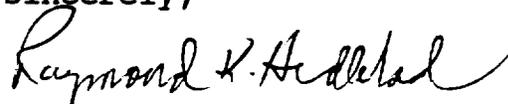
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure and/or injunction, without further notice.

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

**Robert K. Anders, President - Page 2**

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Raymond K. Hedblad, Director,  
Nashville District Office

RKH/k1

**Enclosures:**

FDA-483  
Fresh Air "98"  
21 CFR Part 211

**cc: Randall R. Harville  
Branch Manager  
Holston Gases, Inc.  
1306 Lebanon Road  
Nashville, TN 37210**