



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

d16296  
Food and Drug Administration  
Atlanta District Office  
101

60 8th Street, N.E.  
Atlanta, Georgia 30309

December 12, 1996

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

Paul Dewayne Hutcheson  
Secretary/Treasurer  
Procure Home Health Care Services, Inc.  
511 South Peterson Avenue  
Douglas, Ga. 31533

**WARNING LETTER**

Dear Mr. Hutcheson:

An inspection of your medical oxygen transfilling facility was conducted on November 26, 1996, by investigator B. Douglas Brogden. Investigator Brogden documented several significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal, Food, Drug and Cosmetic Act (the Act).

The following deviations were observed:

- ▶ Failure to have records on hand which document calibration of the [redacted] Oxygen Analyzer 570A. Also, pressure gauges on the filling and on the supply sides of the transfilling manifold have not been calibrated.
- ▶ Failure to document that a purity test had been done on lots of Oxygen USP manufactured from 1/2/96 through 9/17/96, and an identity test on some lots.
- ▶ Failure to establish written procedures covering productions, testing, approval, and rejection of components, labeling, training, and packaging.
- ▶ Failure to have a thermometer available to monitor cylinder temperatures during filling operations.
- ▶ Failure to have in place a written recall procedure to assure that all cylinders have been recovered in the event of a recall.

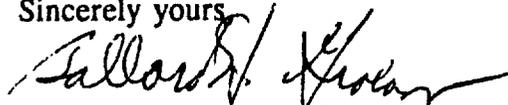
- ▶ Failure to perform adequate prefill operations on each high pressure cylinder, prior to filling.

The above list of deficiencies should not be construed as an all inclusive list of violations that may be in existence at your firm. At the close of the inspection, a list of Inspectional Observations (FDA-483) was issued to you. It is your responsibility to ensure that all requirements of the Act are being met.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law, such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should be addressed to Barbara A. Wood, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director  
Atlanta District