



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

ACI-35 D1169B

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

February 6, 1997

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

Ronald S. Street, Sr.  
President/CEO  
Street Home Medical, Inc.  
1538 Watson Blvd.  
Warner Robins, Georgia 31093

**WARNING LETTER**

Dear Mr. Street:

An inspection of your medical oxygen transfilling facility was conducted on January 16, 1997, by Investigator Jackie M. Douglas. Investigator Douglas 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 drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include identity and purity, prior to release. You have failed to test a cylinder from each manifold filling sequence for identity and purity as required. No differentiation is made between filling sequences for testing purposes. Lot designations are related to changes in supply side H cylinders, as opposed to manifold filling sequences. For example, a review of your recent batch production records revealed that manifold filling sequences were not tested on December 19, December 16, and December 6, 1996.

You failed to properly calibrate the ~~oxygen~~ analyzer utilized for purity analysis on transfilled cylinders. You could provide no assurance that the calibration standard in use was of an appropriate suitability, quality, and purity. The calibration gas in use was a medical grade product. The suitability of this gas could not be determined due to the inadequacy of the "Certificate of Analysis" issued by your supplier. Our investigator also noted your failure to verify the identity of the incoming bulk liquid oxygen received under certificate of analysis from your supplier.

You have failed to establish formalized written procedures which accurately reflect all of the current operations at your facility. The procedures on file were provided by your transfilling equipment manufacturer and are not always indicative of the procedures actually in use. No procedures are included which address the transfilling of liquid oxygen. The procedures also do not address the labeling of transfilled product, labeling controls, recalls, or employee training.

Our investigator also noted the failure to properly conduct prefill inspections on cylinders. Product labeling and lot numbers from previous manufacturers/transfillers were observed on several cylinders recently filled at your firm. Some cylinders were noted to bear labeling from both Street and other manufacturers. Other cylinders bore no Street labeling at all. The investigator also observed an E cylinder with an expired hydrostatic test date. In addition, you have failed to monitor cylinder temperatures during filling. This requirement is included in the filling procedures on file.

At the conclusion of the inspection, Investigator Douglas issued his Inspectional Observations (FDA 483) to and discussed his findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility.

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.

We acknowledge that you voluntarily ceased filling operations until you could institute appropriate product testing. Of particular concern, however, is the fact that the failure to appropriately test your transfilled product (liquid oxygen) was noted in a March 1993 inspection which resulted in the issuance of a previous Warning Letter. 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 address any proposed actions regarding the oxygen products currently in distribution which have not been properly tested. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director  
Atlanta District