



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Atlanta District Office

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

January 5, 1999

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

Ted Shuman, President/CEO  
Shuman HealthCare  
2015 Tebeau Street  
Waycross, GA 31501

**WARNING LETTER**

Dear Mr. Shuman:

An inspection of your medical oxygen transfilling facility located at 3021 Altama Ave., Brunswick, Georgia, was conducted on December 16 & 17, 1998, by Investigators Janet B. Gray, and Brandy E. Davis. Our investigators documented 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).

Significant deviations include, but are not limited to the following:

1. You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate specifications for purity prior to release. Your failure to always document the calibration of the Servomex Oxygen Analyzer since 6/19/98 renders invalid all % purity results obtained with this instrument on those production dates lacking such documentation. Moreover, your *Oxygen Transfill Batch Production Records* for production on 10/5/98 and 11/30/98 do not always contain the actual values obtained upon testing for % purity. Affected lots manufactured on 10/5/98 and 11/30/98 include 10059801, 10059802, 10059803 (15 cylinders), and 11309803 (4 cylinders).
2. There was no documentation available to show that a second responsible individual had reviewed and approved your firm's oxygen transfilling records including the *Oxygen Transfill Batch Production Record*, the *Lot Number Assignment Log*, the *Oxygen Analyzer Calibration Log*, and the labeling record. This deviation becomes extremely important in light of the problems described under item 1 above.

3. You have failed to ensure that each person engaged in the manufacture, processing, and transfilling of Oxygen USP has the education, training, and/or experience to enable that person to perform their assigned functions in such manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. This training must be in the particular operations that the employee performs and include current good manufacturing practice as it relates to the employee's function. During our inspection, our investigators observed that your firm's only transfilling operator was not knowledgeable about the prefill checks required for high pressure cylinders, the location of the calibration logs and the manual for the Servomex Oxygen Analyzer, and labeling requirements. In addition, this individual stated on several occasions that he wasn't sure about the meaning or importance of some of the cylinder checks he was performing. His lack of training is clearly exemplified by his failure to conduct and document several required prefill inspection checks on each cylinder including the hydrostatic testing date, cylinder color, and condition of valve assembly.
4. Your firm has not calibrated and documented the calibration of the various measuring equipment used in the transfilling operation, such as the manifold pressure gauge and the thermometer used for monitoring the filling temperatures of the cylinders.
5. Failure to exercise proper controls regarding the receipt, storage and use of labels for Oxygen USP. These labels were not stored in a secured area, and there were no records documenting their receipt and/or issuance.

Our investigators observed several Oxygen USP cylinders which were available for distribution, and which lacked required labeling such as name and place of business of the manufacturer or distributor, and/or lot numbers. These drug products are misbranded in accordance with section 502(b)(1) and section 502(c) of the Act, respectively.

At the conclusion of the inspection, Investigators Gray and Davis issued their Inspectional Observations (Form FDA 483, copy enclosed), to Ms. Karon P. Hall, Branch Manager, and discussed their findings with her. 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 and any other similar operation under your authority.

You should take immediate action to correct these violations. Failure to promptly correct these violations may result in legal sanctions provided by 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 in writing, within fifteen (15) working days of receipt of this letter, of all steps you have taken, or intend to take, to correct these violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, please state the reason for the delay, and the time within which the corrections will be completed. Your

response should address any proposed actions regarding any oxygen cylinders currently in distribution which have not been properly tested.

Your response should be addressed to Carlos A. Bonnin, Compliance Officer, at the address noted in the letterhead.

Sincerely,

*for*   
Ballard H. Graham, Director  
Atlanta District

Enclosure

cc: Karon P. Hall, Branch Manager  
Shuman HealthCare  
3021 Altama Avenue  
Brunswick, GA 31520