



August 7, 2001

VIA FEDERAL EXPRESS

Paul A. Reed, President
Southeastern Home Oxygen Service, Inc.
1112 15th Street
Columbus, GA 31901

WARNING LETTER
(01-ATL-71)

Dear Mr. Reed:

Investigator Jackie M. Douglas conducted an inspection of your medical oxygen transfilling facility, Southeastern Home Oxygen Service, Inc., Columbus, GA on 7/17 & 19/01. Our investigator documented several significant deviations from the Current Good Manufacturing Practice Regulation (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 U.S.P., to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

You failed to establish and follow written procedures for production and process controls covering all aspects of your firm's operations to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess. For example, you failed to assay the incoming liquid oxygen for identity and strength prior to filling liquid oxygen lots in accordance with your written procedures. There were at least 3 liquid oxygen lots, which were filled prior to conducting the testing of the commingled bulk oxygen lot. Records indicate that your firm received a bulk oxygen lot on 6/8/01 and filled one liquid oxygen lot on 6/8/01. You did not conduct the purity and identity testing of this bulk lot until the following day (6/9/01). Also on 3/27/01, a bulk delivery was received, however testing of the bulk lot was not done until 3/29/01. Two liquid oxygen lots were filled prior to the 3/29/01 filling and testing of the first gaseous lot following the 3/27/01 bulk delivery. Failure to conduct purity and identity testing of the bulk oxygen lot prior to filling liquid oxygen was noted during our previous inspection of your facility in December of 1999.

You failed to maintain documentation demonstrating that the gaseous manifold pressure gauge has been calibrated. You also failed to establish written procedures addressing the instructions and the frequency for the calibration of filling instruments such as the filling manifold vacuum gauge, pressure gauge, and the infrared thermometer. Failure to establish written procedures for the filling instrument calibration was noted during our previous inspection. You also do not have written procedures for odor-testing cylinders with no pressure on them, which are returned by your customers.

You failed to have documentation that the sensitivity and accuracy of the test procedure for the assay of Oxygen, USP using the [REDACTED] analyzer will produce identity and strength results equivalent or

superior to those obtained using the official test procedures. This deficiency was pointed out to you during the previous inspection of your facility in December of 1999.

You failed to document that your monitoring of cylinder temperature during filling includes adjustment for the "emissivity" factor as described in the infrared thermometer's instruction manual. This adjustment relates to the accuracy of the instrument and thus to the accuracy of the temperature obtained during filling. Your employees were not familiar with the "emissivity" instructions for the infrared thermometer.

You failed to assure the adequacy of your firm's current computer distribution tracking system. Review of 2 lots selected at random for comparison of production records with computerized tracking information revealed inconsistencies in the number of oxygen cylinders filled with those distributed.

Inlet and outlet fittings on Oxygen USP [REDACTED] tanks, which are owned by you, were not permanently fixed or otherwise tamper evident. You indicated to our investigator that tanks, which are loaned from a third party, have permanently fixed inlet and outlet fittings and that you will equip your own tanks with permanently fixed fittings.

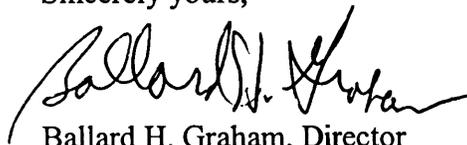
At the conclusion of the inspection, our investigator issued an FDA 483 to Mr. Richard A. Mohny, Vice President. A copy of the FDA 483 is enclosed for your review. Neither the above discussion of deficiencies, nor the Inspectional Observations (FDA 483), should be construed as an all-inclusive list of violations that may be in existence at your facility. It is your responsibility to ensure that all requirements of the Act are met at this and any other similar facility under your authority.

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 warning letters involving drugs so that they may take this information into account when considering the award of contracts.

We request that you notify this office within fifteen (15) working days of receipt of this letter of all steps you have taken, or intend to take, to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. We acknowledge that some corrections were initiated during the course of the inspection, to include obtaining documentation about the equivalency of the [REDACTED] testing procedures to the USP method. Certificates of analysis for the oxygen and nitrogen calibration gases were obtained prior to the close of the inspection. Additionally, you indicated to our investigator that the firm ordered liquid Oxygen labels which were due to arrive on 7/19/01. Your firm did not have liquid oxygen labels. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be addressed to Serene A. Kimel, Compliance Officer, at the address noted in the letterhead. You can also contact Compliance Officer Kimel at 404-253-1296 if you have any questions about this letter.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure