



DEPARTMENT OF HEALTH AND HUMAN SERVICES

**Food and Drug Administration
Atlanta District Office**

ATL-38 mason

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

April 26, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ed G. Carson
Owner
Oconee Medical, Inc.
P.O. Box 6061
Athens, Georgia 30604

WARNING LETTER
(99-ATL-18)

Dear Mr. Carson:

Investigators Lean M. Andrews and Vicky C. Stoakes conducted an inspection of your medical oxygen transfilling facility located in Watkinsville, Georgia, on April 9, 1999. Our investigators 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 medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications prior to release. You have failed to appropriately calibrate and assure the accuracy of the analyzer currently in use. Of the [REDACTED] days on which filling was conducted since November 1998, the [REDACTED] analyzer was only calibrated on four occasions. In addition, there was no operating manual available for this analyzer. You exhibited a lack of familiarity with the required calibration frequency for this machine. A review of the available Batch Production Records created since November 1998, revealed three occasions when no purity assay was recorded for transfilled units.

You have failed to establish and maintain formalized written procedures to cover the various aspects of the transfilling operations at your location. You provided a copy of "Oxygen Transfilling Procedures" to the investigators which reportedly was posted at your previous filling location. No similar procedures have been established for your Watkinsville location, even though you have been relocated for approximately a year. These old procedures were deficient in that they did not provide adequate instruction for the individuals performing transfilling.

You have failed to maintain appropriate batch production and control records to document each significant step in the transfilling of your drug product. No odor testing is recorded on the records maintained. No record is maintained of any of the filling temperatures. In addition to the failure to test for purity on the three days discussed above, these records failed to include any indication of leak testing after filling. None of the production records included any notation to indicate that they had been reviewed and approved by a responsible individual. You indicated to our investigators that you occasionally reviewed production records, although there was no indication that any of the deficiencies discussed above were ever detected during your review. Other missing records noted during the inspection included training records and the Certificate of Analysis for your calibration gas.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a 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 operation that the employee performs and include current good manufacturing practice as it relates to the employee's functions. This lack of training is further evidenced by your practice of performing the hammer test on aluminum cylinders, failure to know the appropriate calibration frequency for your equipment, and lack of familiarity with the odor test.

Further, the Oxygen USP which your firm distributes is considered misbranded in that it is manufactured in an establishment not duly registered under Section 510 of the Act and the oxygen has not been listed as required by Section 510(j). The failure to register was discussed in the Warning Letter issued to you on July 17, 1995 (copy enclosed). That letter also discussed deviations that continue to exist such as the failure to appropriately test your product and the failure to perform appropriate in-process testing on this product. Although we note that you promised correction of these violations by May 9, we question your firm's commitment to implementing these corrections. Our concern is due to the repetitive nature of the violations and to comments made during the course of the inspection. Of particular concern is the initial comment to our investigator that you had not transfilled product for at least six months. This is particularly disturbing as you identified yourself as the most responsible individual as to the day to day operations of this firm and you also indicated that you would periodically review the production records. We would welcome the opportunity to discuss the ongoing violations at your facility at the district office. We feel such a meeting would be advantageous in light of your continued lack of understanding of some of the basic requirements associated with the transfilling of oxygen.

At the conclusion of the inspection, our investigators issued their Inspectional Observations (FDA 483) to you and discussed their findings. I have included drug registration and listing forms, in addition to instructional materials on completing the forms. 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 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.

You are requested to 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. If corrective action cannot be completed with 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should also address any proposed actions regarding any oxygen lots 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. You can also contact Compliance Officer Campbell at (404) 253-1280 to set up a meeting at the district office.

Sincerely yours,


Ballard H. Graham, Director
Atlanta District

Enclosures