



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

AD-35 [Signature]

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

September 13, 2000

VIA FEDERAL EXPRESS

Anthony B. Griffin
President/Owner
JD Medical Services, Inc.
(dba) Griffin Medical Services
798 Red Bud Road
Calhoun, Georgia 30701

WARNING LETTER
(00-ATL-62)

Dear Mr. Griffin:

Investigator Vicky C. Stoakes conducted an inspection of your medical oxygen transfilling facility in Calhoun, Georgia, on August 18 and August 23, 2000. Our investigator documented numerous 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 Compressed, 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. No records were available of any identity or purity testing being performed on any cylinders distributed prior to July 7, 2000. You informed Investigator Stoakes that you had been transfilling for more than three years. For lots filled after July 7 you failed to maintain testing records for 33 additional lots that have been distributed. A review of the analytical records for 34 lots that were tested, found the purity results to be inadequately recorded. The actual purity assay for these lots could not be determined.

You failed to maintain adequate batch production and control records for each batch of Oxygen USP produced, to include required information and documentation of each significant step in the production and testing of each batch. Documentation of the performance of all quality control checks and tests during prefill, filling, and postfill were not recorded for each manifold filling sequence. Prior to July 7, your firm maintained no batch production records or any documentation of the transfilling operation in Calhoun.

Batch records maintained since July 7 were also noted to have serious deficiencies. Each manifold filling sequence, or lot, of Oxygen USP was not clearly identified and tested. No record is maintained of cylinder temperatures and pressures during transfilling. No record was maintained to indicate that hydrostatic test dates are checked prior to filling. No record was maintained of a hammer test being performed on steel cylinders that are still in use. No documentation was available to indicate that any of these transfilling records were reviewed and approved by a responsible individual for adequacy and accuracy prior to lot release.

You have failed to appropriately calibrate and assure the reliability of the analyzer currently in use. You indicated to Investigator Stoakes that prior to July 7 the analyzer was rarely calibrated as required. Our review of the calibration records since then revealed that you failed to perform the weekly calibration called for in the procedures on file. There were several weeks when no calibration was performed. There was no indication that any day of use calibration was being conducted although described in the [REDACTED] procedures on file. You could provide no documentation as to the purity of the calibration gases used to calibrate your analyzer.

You have failed to establish and implement appropriate written procedures for production and process controls to assure that your drug product has the identity, strength, quality, and purity it purports to possess. You have failed to establish written approved procedures to address all critical aspects of the transfilling and quality control operations. The one-page sheet of instructions posted at the transfilling site failed to address all critical manufacturing steps in sufficient detail. You have failed to ensure that your facility followed the established procedures and that your employees understood the procedures on file. Many of the procedures in use were inadequate to include the corrosion test for steel cylinders, lack of hydrostatic test date checks, failure to adequately perform leak testing, and lack of a calibration program for the gauges and thermometer in use.

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 the lack of familiarity with the procedures previously discussed and the number of serious deficiencies noted during the inspection.

At the conclusion of the inspection, our investigator issued her Inspectional Observations (FDA 483) to you and discussed her findings. 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 (such as your Dalton location) 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.

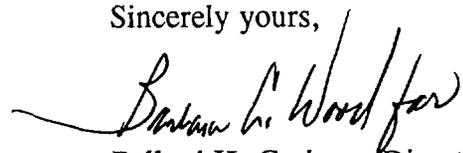
We acknowledge, and are appreciative of, the corrective actions you immediately implemented and promised. These actions included a venting of all cylinders at your facility that were filled prior to July 7 and a promise to stop filling at your Dalton facility until adequate corrections are implemented. We are also in receipt of your letter dated September 1, 2000, which further outlines the corrective actions you plan to implement. In your letter of August 22 you stated that you would retrieve all tanks not in compliance and bring them into compliance. We note that your September 1 letter fails to mention that commitment.

During the inspection you stated that your manufacturing activities prior to July 7 were inconsistent, filling activities were not documented, and all lots were not tested for purity. You also acknowledged complete responsibility for these failures, expressed your desire to comply with all regulations, and promised immediate corrections to all deficiencies noted. We fully expect you to stand behind all verbal promises made to Investigator Stoakes during the inspection and any written commitments sent to FDA since that time.

You are requested to notify this office within fifteen (15) working days of receipt of this letter of all additional 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 within 15 working days, state the reason for the delay and the time within which corrections will be completed. Please address adulterated lots currently in distribution in that response.

We would also request that you notify this office when you plan to resume transfilling of Oxygen USP at the Calhoun and Dalton locations. 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 if you have any questions about this letter.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District