



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Food and Drug Administration  
Atlanta District Office

HC-35M3442

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

February 24, 2000

**VIA FEDERAL EXPRESS**

Ashley Denton  
Chairman of the Board  
Satilla Health Services, Inc.  
410 Darling Avenue  
Waycross, Georgia 31501

**WARNING LETTER**  
(00-ATL-24)

Dear Mr. Denton:

Investigator B. Douglas Brogden conducted an inspection of your medical oxygen transfilling facility, Satilla Home Care, located at 2501 Plant Avenue in Waycross, Georgia, between January 26 and February 3, 2000. Our investigator 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 reliability of the analyzer currently in use. The [REDACTED] Oxygen Analyzer had not been shown to be equivalent to the USP test method. You could provide no documentation that the sensitivity and accuracy of this analyzer would produce the identity and strength results equivalent or superior to those obtained using the official test procedure. You also have failed to always document the calibration of the analyzer prior to being used to perform testing of lots of Oxygen USP prior to distribution.

You have failed to establish adequate written procedures for production and process controls to assure that the drug product you distributed had the identity, strength, quality, and purity it purported or was represented to possess. The procedure manual in use was a compilation of a generic manual provided by your oxygen equipment distributor and a copy of procedures from another home health care facility. The procedures had not been appropriately reviewed and updated to reflect the actual procedures and unique operations in effect at your facility. Some examples of these conflicting procedures include the cylinder Refilling Procedure, the procedure for calibrating the analyzer, and the procedure for testing of filled cylinders.

You have failed to ensure that your facility followed the established procedures and that your employees understood the procedures on file. You have failed to officially designate a Quality Control Unit which had the responsibility, authority, and training to approve or reject all drug product and other critical responsibilities described in your Quality Assurance Tester Procedure. You have failed to follow maintenance and service procedures for the filling manifold, pigtails, valve seats, and connections on the manifold, at the frequency described. You have not assigned unique lot numbers for each manifold filling sequence as described in the Satilla Transfill Policies And Procedures. You have failed to maintain a master label inventory in accordance with your procedure for the Inventory Log For Oxygen Labels.

You failed to maintain adequate batch production and control records for each batch of Oxygen USP produced, to include required information relating to the production of each batch. Documentation of the performance of all quality control checks and tests at prefill, filling, and postfill were not recorded for each manifold filling sequence. This was noted on production days when multiple manifolds were filled. All drug production and control records were not being reviewed and approved by a responsible individual prior to batch release. Several batch production records were noted not to have been signed off indicating review. These production dates included 11/19/99, 12/2/99, 12/8/99, 12/16/99, 12/31/99, 1/14/00, and 1/21/00. The Oxygen Receipt Log was also not signed off by a reviewing official. Of particular concern however were initials on the Oxygen Analyzer Calibration Log indicating review and approval when there were no calibration records available. This was noted on 11/19/99, 12/31/99, 1/14/00, and 1/21/00.

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. Only one employee record was found documenting a review of your firm's oxygen transfilling policies and procedures. This lack of training is further evidenced by the lack of familiarity with the procedures previously discussed.

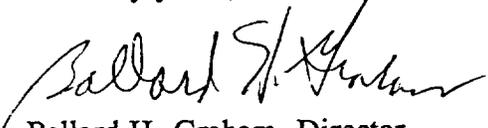
At the conclusion of the inspection, our investigator issued his Inspectional Observations (FDA 483) to Benjamin R. Wheeler, Director of Satilla Enterprises, and discussed his findings. A copy of the FDA 483 is enclosed for your review. Neither the above discussion of deficiencies, nor the FDA 483, should 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.

We acknowledge, and are appreciative of, the corrective actions immediately implemented by Mr. Wheeler. These actions included a termination of filling activities at Waycross and the initiation of a recall of Oxygen USP filled at this location. 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 with 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should also include a status of the recall to date. We would also request that you notify this office when you plan to resume transfilling of Oxygen USP at the Waycross location. 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,

A handwritten signature in black ink, appearing to read "Ballard H. Graham". The signature is fluid and cursive, with a large initial "B" and "G".

Ballard H. Graham, Director  
Atlanta District

Enclosure

cc: Ronald Hayes  
Manager  
Satilla Home Care  
2501 Plant Avenue  
Waycross, Georgia 31501