



DEPARTMENT OF HEALTH AND HUMAN SERVICES

44 pgs
3/25/98
Food and Drug Administration
Atlanta District Office

FOI 91475b
60 8th Street, N.E.
Atlanta, Georgia 30309

February 18, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Steve Elrod, President
Oxy Plus, Inc.
5300 Oakbrook Parkway
Suite 220
Norcross, Georgia 30093

WARNING LETTER

Dear Mr. Elrod:

An inspection of your medical oxygen transfilling facility, Home-Ox Medical, Inc. located in Gainesville, Georgia, was conducted on January 15, 16, & 21, 1998, by Investigator Stephanie E. Hubbard. 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 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 maintain Certificates of Analysis for all liquid oxygen used to fill units at the homes of your customers. Although your truck mounted vessel is filled approximately [REDACTED], you could provide only approximately ten Certificates of Analysis. As no additional testing is performed on this product, these Certificates are the only record that the product was appropriately tested and serve as the only documentation that the testing conducted by your supplier was witnessed by an employee of your firm. Several lot numbers of oxygen identified as being transfilled on the premises are not documented on the Oxygen Purity Log as being tested. These include lot numbers 441K729, NI8L56, and N29J48.

The required calibration steps were not performed on your [REDACTED] Analyzer each day of use. A comparison of the Calibration Log and the Purity Log reveals several discrepancies. Oxygen is documented as being analyzed on 5/7/97, 5/14/97, 5/21/97, 5/28/97, 6/4/97, 6/11/97, and 6/18/97, although there is no indication that the [REDACTED] was calibrated on those dates. There were no entries in the Oxygen Purity Log or the Calibration Log between November 27, 1997 and January 14, 1998, although product was transfilled and delivered during that time period.

You have failed to establish formalized written procedures to cover the various aspects of your transfilling operation. The only procedures available were grossly inadequate and were not indicative of the operations currently conducted at your firm. The only filling procedures which could be located consisted of an undated, unsigned document posted next to the analyzer. This procedure stated that truck mounted vessels would be analyzed, oxygen would bear a four month expiration date, and required records would be retained for six years. Although your management was aware that truck vessels were not being tested, they exhibited no familiarity with the other two requirements. It was not readily apparent that these procedures had been read by responsible individuals at your facility. Some additional procedures were sent over from the Norcross office during the inspection. These procedures were not being followed at the Gainesville site, the employees were not familiar with these procedures, and there was no indication that these procedures had been approved by a responsible reviewing official.

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 operations that the employee performs and include current good manufacturing practice as it relates to the employee's functions. In fact there was no documentation available to indicate that anyone at the firm had received training commensurate with their responsibilities.

This lack of training was exemplified by the total absence of meaningful procedures, the failure to maintain appropriate testing records, the deficiencies noted in the production records maintained, and the lack of familiarity with GMP requirements exhibited by your employees. Our investigator was informed that production records had been discarded and that weekend "emergency" fills were not documented on any logs. Fill logs were reported to be routinely discarded after approximately two months. These records should be retained for at least one year after the expiration date of the batch.

There was no documentation available that all production, control, and testing records were being properly reviewed prior to batch release. Many of the discrepancies noted above should have been noted if the records had been reviewed by a responsible individual at the firm. Two assay results noted on 8/28/96 and 9/4/96 failed to meet the minimum purity requirements for Oxygen USP. In addition, two assays performed on 8/7/96 and 8/21/96 failed to meet the standard established in the procedures sent over from the Norcross office. Those procedures state that any oxygen product which assays below [REDACTED] should be recalled. There is no indication that any of these lots were retrieved from distribution.

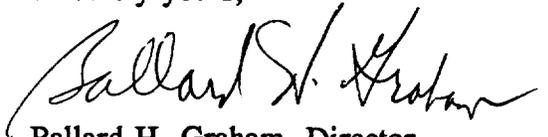
At the conclusion of the inspection, Investigator Hubbard issued her Inspectional Observations (FDA 483) to and discussed the findings with Jack W. Haire, General Manager. A copy of the FDA 483 is enclosed for your review. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your 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. The failure to have appropriate written procedures and deficient analytical testing records were brought to the

attention of Mr. Haire during the previous inspection conducted in May 1996. Appropriate corrective action was not taken as a result of that inspection.

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 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 within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should 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.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District

Enclosure

cc: Jack W. Haire
Manager
Home-Ox Medical, Inc.
640 Spring Street
Gainesville, GA 30501