



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Atlanta District Office

HFI-35

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

February 26, 1998

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

J. Cornell Osborne  
President  
Osborne Medical Inc.  
153 Altama Connector  
Brunswick, Georgia 31525

**WARNING LETTER**

Dear Mr. Osborne:

An inspection of your medical oxygen transfilling facility was conducted on February 5, 1998, by Investigator Janet B. Gray. 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 maintain records of purity testing for all lots on each date of filling. No purity test records were available for cylinders filled on 1/13/98, 12/4/97, 11/24/97, and 1/8/97. In addition, you have failed to test one cylinder from each manifold filling sequence. A review of your filling records indicated that only one cylinder was tested each day, even in instances when up to [REDACTED] filling sequences had occurred on that date. Your Batch Production Record states that at least one cylinder will be tested each time cylinders are changed on the manifold.

You have failed to document the required calibration steps for the [REDACTED] Analyzer on each day of use. No records were available documenting the calibration of the analyzer on any date prior to use.

You have failed to maintain appropriate documentation that each significant step in the production and testing of this product has been conducted as required. The Batch Production Records were incomplete and contained numerous omissions such as prefill, fill, and post fill checks. Several records also lacked any indication that they had been reviewed or approved by a responsible individual prior to release of the oxygen. Many of these discrepancies should have been noted if the records had been properly reviewed. There was no available documentation

that any of the available written procedures had been reviewed and approved by a responsible individual at the firm.

You have failed to establish clearly defined storage areas for cylinders to properly segregate quarantined, empty and released cylinders. A quarantined defective cylinder was noted to be stored in the same rack as other empty cylinders to be used. There were also no clearly identified areas for filled cylinders which were noted to be stored in the same area as empty cylinders.

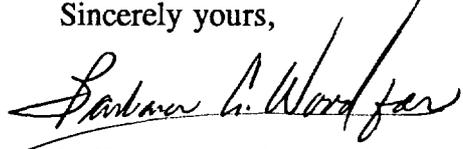
A review of your transfilled product labeling currently in use revealed that it fails to include the required statement "Caution: Federal law prohibits dispensing without a prescription." Oxygen USP is regarded to be a prescription drug and would be considered to be misbranded if its label fails to include this statement.

At the conclusion of the inspection, Investigator Gray issued her Inspectional Observations (FDA 483) to and discussed the findings with you. 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. These inspectional findings are particularly disturbing due to the fact that you were issued a Warning Letter in June 1995. That letter addressed analyzer calibration deficiencies and your lack of written procedures. Although corrective action was noted during our October 1995 inspection, you have failed to exhibit the diligence required to maintain an appropriate level of compliance.

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 be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Ballard H. Graham".

Ballard H. Graham, Director  
Atlanta District