



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
7200 Lake Ellenor Drive  
Orlando, Florida 32809

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

**WARNING LETTER**

FLA-97-87

September 30, 1997

Randall L. Wright, R.R.T., President  
Oxygen & Respiratory Therapy, Inc.  
2828 Clark Road, #1  
Sarasota, Florida 34231

Dear Mr. Wright:

Inspection of your medical gas filling operation on September 15-16, 1997, by FDA investigator Christine M. Humphrey, revealed serious violations of the Federal Food, Drug, and Cosmetic Act (the Act). The investigator documented significant deviations from the Current Good Manufacturing Practice (CGMP) Regulations for drugs [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)] in conjunction with the testing and release for distribution of compressed medical oxygen causing the products to be adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Inspection revealed there is no assurance that your medical oxygen products meet applicable standards of identity, strength, quality, and purity in that you have failed to test each component lot of bulk compressed oxygen to determine conformance with appropriate specifications prior to use, or in lieu of testing, receive a valid certificate of analysis from your supplier and conduct an identity test. Refilled cylinders of compressed medical Oxygen USP from each uninterrupted filling sequence are not being tested for purity and identity prior to release for distribution.

Written procedures are not established for production and process controls designed to assure that your medical oxygen products have the identity, strength, quality, and purity they are represented to possess. For example, no written procedures are established for calibration and maintenance of equipment, prefill, fill, and postfill of cylinders, analytical testing, labeling, handling of complaints, and there is no assurance that personnel have received adequate CGMP training.

Batch production and control records are incomplete, inaccurate, and fail to document that each significant step in the manufacturing operation was completed, such as all required pre and post fill cylinder inspections and testing. Your firm's manifold equipment is capable of filling a maximum of five cylinders per uninterrupted filling sequence. The investigator documented that all existing batch records show seven or more cylinders filled with only one assay for purity and identity documented. Your batch record for September 11, 1997, shows 12 cylinders filled with no pre and post fill cylinder inspections, and no testing for purity and identity. In addition, two full cylinders of Oxygen USP being held for distribution were observed to bear lot numbers that identified the cylinders as being filled on September 9 and 10, 1997. However, there are no batch records documenting the transfilling of these cylinders on those dates.

Other Federal agencies are routinely advised of Warning Letters issued so that they may take this information into account when considering the award of contracts. Additionally, pending applications for Agency approval (NDA, ANDA, SNDA, etc.) or export approval requests may not be approved.

In order to facilitate the Food and Drug Administration (FDA) in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other Federal agencies concerning the award of government contracts, and to resume review of any pending applications, we request that you notify this office when corrective actions are completed and you believe your facility is in compliance with the CGMP regulations so that a verification inspection can be scheduled.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. As president, it is your responsibility to ensure that all medical gas products you repack and distribute are in compliance with the Act and the requirements of the CGMP regulations. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

We request that you notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 7200 Lake Ellenor Drive, Suite 120, Orlando, Florida 32809, telephone (407) 648-6823, extension 263.

Sincerely,



Douglas D. Tolen  
Director, Florida District