

4/2/98

HF1-35

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration  
d18036

Refer to: CFN 1123546

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4040

April 29, 1998

**WARNING LETTER**

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

Mr. Thomas L. Robertson, President  
At-Home Care, Inc.  
Carilion Health Systems  
P.O. Box 12946  
Roanoke, Virginia 24029

Dear Mr. Robertson:

The Food and Drug Administration (FDA) conducted an inspection of your Oxygen U.S.P. manufacturing facility in Roanoke, Virginia facility on April 9, 1998. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Liquid and Compressed Oxygen U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), and include the following:

1. Failure to have the appropriate documentation to demonstrate that each batch of Liquid Oxygen is in conformance with appropriate specifications for identity, strength, quality, and purity it purports or is represented to possess prior to release.
2. Failure to calibrate and or document the calibration of the oxygen analyzer, thermometer, and pressure gauge used during testing and transfilling of Oxygen U.S.P.
3. Failure to perform or have appropriate documentation to demonstrate that adequate pre-fill, fill, and post-fill operations were performed on each high-pressure cylinder and home cryogenic unit filled.
4. Failure to have a second individual verify the accuracy and completeness of batch production records for Liquid and Compressed Oxygen U.S.P.

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5. Failure to identify each high-pressure cylinder of Oxygen U.S.P. with a lot or control number that permits determination of the history of manufacture and control of the batch and reflects each manifold filling sequence.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on form FDA-483 (enclosed). Your response appears adequate where it addresses those observations issued to Mr. Edward J. Heath at the close of the inspection. However, we have reviewed your firm's Liquid and Compressed Oxygen Transfill Procedures that Mr. Heath submitted as part of the response and have attached our comments.

The aforementioned violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Federal agencies are advised of the issuance of all Warning Letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer.

Sincerely,



ELAINE KNOWLES COLE  
Director, Baltimore District

Enclosures