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**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

Refer to : CFN 1122662

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

December 19, 1997

**WARNING LETTER**

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

Mr. Thomas E. Inman, II, President  
Respiratory Home Care of Virginia, Inc.  
11842 Canon Boulevard  
Newport News, Virginia 23606

Dear Mr. Inman:

During an inspection of your Newport News, Virginia facility conducted by the Food and Drug Administration (FDA) on December 11, 1997, 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). The deviations included the following:

1. Failure to assay or have other appropriate documentation to demonstrate that each filled high-pressure cylinder of Oxygen, U.S.P. and each batch of Liquid Oxygen is in conformance with appropriate specifications for the identity, strength, quality, and purity it purports or is represented to possess prior to release.
2. Failure to establish adequate review of the oxygen transfilling batch records for each batch of Oxygen, U.S.P. and Liquid Oxygen and to periodically verify the reliability of the supplier's analysis.
3. Failure to assure and document that each person engaged in witnessing the testing and filling of liquid oxygen and the filling of compressed medical oxygen, has the education, training, or experience to enable that person to perform the assigned function.

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4. Failure to store labeling in a secure location and to document the quantities of Oxygen, U.S.P. labeling issued, used, and returned.
5. Failure to document and/or calibrate the scales, temperature gauges, and pressure gauges used during the transfilling of Oxygen, U.S.P.
6. Failure to establish written procedures to periodically verify the reliability of the supplier's analysis for the testing of cryogenic units after repair and maintenance, and for accurate, dated, and signed review of batch production or control records documentation.

At the conclusion of the inspection, a written list of inspectional observations (FDA-483, enclosed) was issued to Ms. M. Joyce Shelton, Operations Manager.

The above listed 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.

You should 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.

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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. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Elaine Knowles Cole  
Director, Baltimore District

Enclosures

cc: Virginia Board of Pharmacy  
6606 West Broad Street  
Richmond, VA 23230-1717