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DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: CFN/FEI 1123707

Public Health Service

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

DSB

01-BLT-11

January 12, 2001

WARNING LETTER**CERTIFIED MAIL**
RETURN RECEIPT REQUESTED

Ms. Victoria L. Williams, President
Lynchburg Respiratory Care, Inc.
2000 Tate Springs Road
Lynchburg, Virginia 24501

Dear Ms. Williams:

A Food and Drug Administration (FDA) inspection was conducted on January 2 - 3, 2001 at your medical gas manufacturing facility, Respiratory Care & Medical Supply Company, Inc., 4262 S. Amherst Highway, Suite 100, Madison Heights, Virginia. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements, Title 21, Code of Federal Regulations (CFR), Part 211, were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding, do not conform to GMP regulations.

The deviations included the following:

- Failure to test each batch of drug product for conformance to final specifications prior to release, in that 16 lots of Oxygen, U.S.P., manufactured between June and September 2000, were not tested for identity and strength.
- Failure to calibrate laboratory instruments to assure that components, in-process materials, and drug products conform to appropriate standards of identity, strength, quality and purity, in that there was no documentation that the oxygen analyzer was calibrated on September 29 and October 2, 2000.
- Failure to document each significant step in the manufacture, processing, packing or holding of drug products, in that "fill checks" of temperature and pressure for Oxygen, U.S.P., manufactured on August 23, September 11, and October 6, 2000, were not documented.

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- Failure to perform and/or document the review of batch production records by the quality control unit to determine compliance with all established, approved written procedures before release or distribution of a batch.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the close of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding contracts. By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection revealed significant violations of 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 being initiated by the FDA without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent recurrence. If corrective action cannot be completed within 15 working 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. Mr. MacIntire can be reached at (804) 379-1627, extension 14.

Sincerely,



Lee Bowers
Director, Baltimore District