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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

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Refer to: CFN 1122627

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

October 13, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Stephen P. Griggs, President
Rotech Medical Corporation
4506 L. B. McLeod Road, Suite F
Orlando, Florida 32811

Dear Mr. Griggs:

The Food and Drug Administration (FDA) conducted an inspection of your Omega Medical Equipment, Mountain Air Services, Inc., Pennington Gap, Virginia facility on September 22, 1998. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (CGMP), (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211), were observed. These deviations cause your Oxygen, USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations include the following:

1. Failure to follow written production procedures.
2. Failure to maintain batch and production control records.
3. Failure to establish accurate and complete batch production records for each batch of Oxygen, USP, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished.
4. Failure to identify each batch or lot of product with control numbers which permits the determination of the history of manufacture.
5. Failure to maintain a complete drug master record, as the specified product labels do not include mandatory labeling statements. For example, "For emergency use only when administered by properly trained personnel for oxygen deficiency and resuscitation. For all other medical applications, Caution: Federal law prohibits dispensing without prescription."

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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.

We appreciate your voluntary correction of some of the above deviations. Your corrections included destroying the medical oxygen cylinders on the premises during the inspection by venting; your intended recall of E, D, and M6 cylinders; your decision to cease manufacturing medical oxygen; and canceling your drug registration for this facility. We have documented these actions in our records. You should complete your recall of the oxygen cylinders, however, prior to any permanent closing of this facility.

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 CGMP 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, Northern Virginia Resident Post, 101 West Broad Street, Suite 400, Falls Church, Virginia 22046, to the attention of Gerald W. Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504.

Sincerely,



Andrew Bonanno

Acting Director, Baltimore District

Enclosure

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cc: Ms. Barbara D. Daugherty, Regional Manager
Omega Medical Equipment
Mountain Air Services, Inc.
602 West Morgan Street, Suite #2
Pennington Gap, Virginia 24277

