



Food and Drug Administration
Denver District Office
Building 20 - Denver Federal Center
P. O. Box 25087
Denver, Colorado 80225
TELEPHONE: 303-236-3000

October 3, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. William Kennedy, CEO
Rotech Medical
4506 L.B. McLeod Road
Suite # F
Orlando, Florida 32811

RECEIVED

Ref. # - DEN-98-01

Dear Mr. Kennedy:

During an inspection of your firm, Valley Home Medical, Inc., 101 North Fort Lane, Layton, Utah on August 7 - 8, 1997, Consumer Safety Officer David J. Gallant determined that your firm transfills Liquid Medical Oxygen U.S.P. to patient home units. Medical Oxygen is a drug product as defined by section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that your product, Oxygen U.S.P., is adulterated under section 501(a)(2)(B) of the Act in that the controls used for the manufacturing, processing, packing, or holding of this product are not in conformance with current good manufacturing practice regulations (GMPs) under Title 21, Code of Federal Regulations (21 CFR), parts 210 and 211. Deviations noted during the inspection included, but were not limited to the following:

1. Failure to test each lot of incoming bulk oxygen to determine conformance with appropriate specifications for purity, identity and strength [21 CFR 211.84(d)(2)]. For example, your firm failed to obtain valid certificates of analysis for each vessel supplied by [X X X X X], document the witnessing of the testing of the bulk liquid oxygen or perform an identity test on each vessel received or filled by the supplier. Your firm has also failed to establish the reliability of the bulk supplier through periodic audits of their analytical methodology.
2. Failure to provide training sufficient to enable employees to perform their assigned functions [21 CFR 211.25(a)]. For example, there is no written evidence that employees have received proper training in the transfilling of medical oxygen.

3. Failure to maintain records which are required to be held [21 CFR 211.180]. For example, written prescriptions were not available for medical oxygen supplied to nursing home patients.
4. Failure to perform and document adequate pre-fill operations on each medical oxygen cylinder, prior to filling [21 CFR 211.84(d)(3)]. For example, there are no procedures or records which show that the product label is inspected prior to filling.
5. Failure to review and approve all drug product production and control records, to determine compliance with all established, approved written procedures, and to explain and investigate any discrepancy or the failure of a batch or any of its components to meet any of its specifications [21 CFR 211.192]. For example, patient fill records are not being reviewed by a second individual and various discrepancies were noted regarding the dates of delivery and product delivered.
6. Failure to follow written production and process control procedures in the execution of various production and process control functions [21 CFR 211.100(b)]. For example, your firm has failed to follow your standard operating procedures in that patient fill records do not contain the full patient address and signature of the Delivery Technician as required and liquid oxygen maintenance checklists are not being filed in the Oxygen Log Book under the liquid oxygen unit's serial number. Also, Infusion Control Device Maintenance Logs are not being maintained to document the location and maintenance history of the Liberator home cryogenic vessels leased to patients.
7. Failure to review and approve written procedures for production and process control in order to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess [21 CFR 211.100(a)]. For example, there is no documentation that Liquid Oxygen Filling Procedure, Liquid Oxygen Maintenance Policy and Procedure or Recall Policy have been reviewed or placed under formal revision control.

At the conclusion of this inspection, Consumer Safety Officer Gallant issued a written report of observations (FDA 483) to Ms. Annette Howell, Operations Manager. A copy of that report is enclosed for your reference.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. As Chief Executive Officer, it is your responsibility to assure adherence with all requirements of the Act and Good Manufacturing Regulations.

These deviations may be indicative of corporate wide non-compliance. We recommend that internal audits be conducted at all your medical gas facilities and appropriate action be taken to assure that similar violations are not occurring at other locations.

By copy of this letter, we are advising the Health Care Financing Administration (HCFA) that our inspection of your firm 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.

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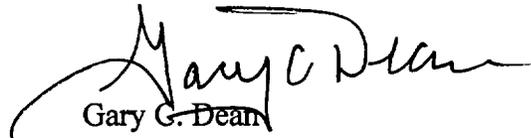
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I am enclosing a copy of the Food and Drug Administration's booklet entitled Compressed Medical Gases Guideline; a copy of the Federal Food, Drug, and Cosmetic Act; a copy of the Fresh Air '97 speech by Mr. Duane Sylvia of FDA's Center for Drug Evaluation and Research; and 21 CFR 211. The Compressed Medical Gases Guideline contains useful information on how to comply with the requirements of 21 CFR 211.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action, including seizure or injunction, without further notice. Federal agencies are advised of the issuance of all warning letters so that they may take this information into account when considering the award of contracts.

Please advise this office in writing, within fifteen (15) working days after receipt of this letter, of the specific actions you have taken to correct the violations. Your response should include: (1) each step that has or will be taken to completely correct the current violations and prevent the recurrence of similar violations; (2) the time when correction will be completed; (3) any reason why the action is not completed within the response time and (4) any documentation necessary to indicate correction has been achieved. Your response should be directed to Ms. Regina A. Barrell, Compliance Officer, at the above address.

Sincerely,


Gary G. Dean
District Director

Enclosures:
As Stated in Letter

cc: Ms. Annette Howell
Operations Manager
Valley Home Medical, Inc.
101 North Fort Lane
Layton, Utah 84041

Ms. Mary Kay Smith
Regional Administrator
Health Care Finance Administration, DHHS Region VIII
Byron G. Rogers Federal Building
1961 Stout Street, Fifth Floor
Denver, Colorado 80294-3538

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