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PS 12/14/97

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

706

CFN 1124688

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

December 5, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James Liken, President
Liken Home Medical, Inc.
1271 Pineview Drive
Morgantown, West Virginia 26505

Dear Mr. Liken:

The Food and Drug Administration (FDA) conducted an inspection of your Morgantown, West Virginia facility on November 10, 1997. 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). The deviations included the following:

1. Failure to assay or have other appropriate documentation to demonstrate that each batch of Liquid Oxygen and filled high-pressure cylinder of Oxygen, U.S.P. 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 calibrate or document the calibration of the oxygen analyzer in accordance with the manufacturer's instruction manual.
3. Failure to assure and document that each person engaged in witnessing the testing and filling of liquid oxygen and 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 establish adequate batch production records for each batch of Oxygen, U.S.P., including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished at the time of performance. [21 CFR 211.188(b)]

At the conclusion of the inspection, Mr. Darren D. Hern, Site Coordinator, was given a written list of inspectional observations (Form FDA 483, enclosed) which was discussed with him. Enclosed is a compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

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.

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.

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, Ext. 14.

Sincerely,



Loveen M. Beck
Acting Director, Baltimore District