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Food and Drug Administration
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Refer to: CFN 1123626

97-BLT-5

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

November 5, 1996

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ronald L. Young, President
Medical Services of America, Inc.
171 Monroe Lane
Lexington, South Carolina 29072

Dear Mr. Young:

The Food and Drug Administration (FDA) conducted an inspection on October 4, 1996, of your Medi-Home Care facility located in Roanoke, Virginia. 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, which cause your 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), included the following:

1. Failure to adequately test each batch of Oxygen, U.S.P. for conformance to final specifications for the drug product, prior to release. Your firm does not document the calibration of the oxygen analyzer. [21 CFR 211.165(a)]
2. Failure to adequately calibrate the oxygen analyzer in accordance with the manufacturer's instruction manual. Your firm fails to document the calibration of the oxygen analyzer. [21 CFR 211.160(b)(4)]
3. Failure to calibrate the pressure gauge used during transfilling of Oxygen, U.S.P. [21 CFR 211.160(b)(4)]
4. Failure to establish adequate written procedures for the production and process controls covering pre-fill, fill, and post-fill operations, equipment calibration, and labeling control, designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess. [21 CFR 211.100(a)]

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5. Failure to establish written procedures designed to assure that correct labels and labeling are used, including identification of the drug product with a lot or control number that permits determination of the history of the manufacture and control of the batch. Your cylinders fail to have the assigned lot number for each manifold filling sequence... [21 CFR 211.130(c)]
6. Failure to perform adequate pre-fill, fill, and post-fill operations on each high-pressure cylinder filled. Your firm's batch production records failed to document that venting, hammer test, valve check, label check, temperature check, and color identification were performed on each cylinder filled. [21 CFR 211.84(d)(3)]
7. 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. Your batch production records lacked the required pre-fill, fill, and post-fill operations performed on each cylinder filled. [21 CFR 211.188(b) and 211.194(d)]

At the conclusion of the inspection, a written list of Inspectional Observations (FDA-483, enclosed) was issued to Mr. David R. Palmer, 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 about 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.

Sincerely,



Kenneth C. Shelin
Director, Baltimore District

Enclosures

cc: Mr. David R. Palmer, Manager
Medi-Home Care
2514 Franklin Road, SW
Roanoke, Virginia 24014

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

bcc: EI file, HFR-MA1, HFR-MA200, HFR-MA240 (Simmons), HFR-MA250, HFA-224,
HFC-210, HFI-35 (purged), HFC-240, HFD-300, HFR-MA2545, HFR-MA2550,
HFR-MA295, HFR-SE150, SJM

Mr. Dennis Carroll
Associate Regional Administrator
HCFA
Room 3100
3535 Market Street
Philadelphia, PA 19101 (purged)