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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Refer to: CFN 1122407

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

May 28, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Richard H. Graham, CEO
Augusta Health Care, Inc.
d.b.a. Care Home Medical
93 Sports Medicine Drive
P. O. Box 1000
Fishersville, Virginia 22939

Dear Mr. Graham:

The Food and Drug Administration (FDA) conducted an inspection of your Fishersville, Virginia facility on May 12, 1998. During the inspection, the following deviations from Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed, which cause your Liquid and Compressed Oxygen USP to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act):

1. Failure to assure that each batch of Oxygen USP is in conformance with appropriate specifications for identity, strength, quality, and purity it purports or is represented to possess prior to release.
2. Failure to calibrate or to document the calibration and routine maintenance of the analyzer used to test Oxygen USP.
3. Failure to assure that each person engaged in the transfilling of compressed medical oxygen has the training in your written procedures as they relate to the employee's functions.
4. Failure to perform and/or to document the pre-fill, fill, and post-fill operations on each high-pressure cylinder and cryogenic vessel filled.

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5. Failure to establish 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 at the time of performance and verified for accuracy and completeness by a second individual.
6. Failure to establish written procedures for the production and process controls designed to assure that Compressed and Liquid Oxygen USP has the identity, strength, quality, and purity it purports or is represented to possess.
7. Failure to establish written procedures designed to assure that filled in-process product containers are identified when set aside and held in unlabeled containers for future labeling operations.
8. Failure to identify the oxygen container with a lot or control number that permits determination of the history of manufacture and control of the batch.

At the conclusion of the inspection, Mr. Robert A. Kirby, Director, was given a written list of inspectional observations (FDA-483, enclosed) which was discussed with him. We acknowledge your decision to recall lots of Oxygen USP from the market due to the significant GMP deviations listed above.

The aforementioned 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. Enclosed is a document provided by FDA National Expert, Mr. Duane Sylvia, titled "FRESH AIR '98" which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

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Please notify this office in writing, within 15 working days of receipt of this letter, of specific steps 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, extension 14.

Sincerely,



ELAINE KNOWLES COLE
Director, Baltimore District

Enclosures

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