



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: FEI 3001610715

930854

Public Health Service

Food and Drug Administration
Baltimore District Office
6000 Metro Drive, Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454

FAX: (410) 779-5707

02-BLT-04

November 20, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Samuel J. Helmick, President
Home Health Care Services Incorporated
1416 MacCorkle Avenue
Charleston, West Virginia 25303

Dear Mr. Helmick:

A Food and Drug Administration (FDA) inspection was conducted on October 29 - 31, 2001 at your medical gas manufacturing facility located at Charleston, West Virginia. Medical gases are drug products as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

During our inspection, deviations from the Current Good Manufacturing Practice (GMP) requirements Title 21, Code of Federal Regulations (21CFR), Part 211 were observed. These deviations cause your medical gases to be adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in or the facilities or controls used for their manufacturing, processing, packing, storage, or holding are not in conformance with GMP regulations.

The deviations included the following:

- Failure to establish and document the responsibilities of and the written procedures for the Quality Control Unit (QCU). For example, there were no written standard operating procedures (SOPs) detailing how or when the various QCU functions will be performed. Those functions specific to the QCU include, re-testing of components, written procedures, in-process sampling and testing, reprocessing, laboratory controls, testing and release for distribution, and complaint files.
- Failure to follow written SOPs for the training of personnel involved in the transfilling of Oxygen U.S.P., in that training documentation, as required by SOPs, was not available for two of the three employees who transfill Oxygen U.S.P.
- Failure to establish and maintain complete laboratory records for the calibration of instruments used in the manufacture and testing of Oxygen U.S.P. For example, there was no documentation

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available for the "Weekly Oxygen Analyzer Service", "Cylinder Thermometer Calibration", and "Annual Pressure Gauge Service," as required by SOPs.

- Failure to establish accurate and complete 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. For example, fill temperature and pressure checks of cylinders and vacuum purge of cylinders, prior to filling, were not always documented.
- Your Oxygen USP labels fail to bear, at a minimum, "RX only." Lack of the prescription legend misbrands your medical Oxygen, U.S.P.
- Failure to establish and maintain complete written procedures for production and process controls, in that there were no approved written procedures for the warehousing of drug products that included procedures for the quarantining of finished products, prior to release and distribution. Additionally, the written procedures for "Labeling and Marking" do not address receipt, identification, storage, handling, or examination of labeling.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to all requirements of the Act and regulations at your facility. The specific violations noted in this letter and in the Form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If you determine the causes to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters concerning drug products so that they may take this information into account when awarding 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. These actions include, but are not limited to, seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working 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

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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,

A handwritten signature in black ink, appearing to read 'LB', with a long horizontal flourish extending to the right.

Lee Bowers
Director, Baltimore District

cc: Ms. Patricia Harris
Regional Administrator
Health Care Finance Administration
Suite 216, The Public Ledger Building
150 South Independence Mall West
Philadelphia, Pennsylvania 19106 (purged)