



DEPARTMENT OF HEALTH AND HUMAN SERVICE

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Public Health Service

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Food and Drug Administration  
Baltimore District Office  
900 Madison Avenue  
Baltimore, MD 21201-2199  
Telephone: (410) 962-4017  
FAX: (410) 962-2219

November 2, 1998

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Gordon Barlow, CEO  
Chief Executive Officer  
Home Health Clinical Services  
5701-D General Washington Drive  
Alexandria, Virginia 22312

Dear Mr. Barlow:

A Food and Drug Administration (FDA) inspection was conducted from October 15, 16, 19 & 20, 1998 at your medical gas manufacturing facility, Home Health Clinical Services, Inc., 5701-D General Washington Drive, Alexandria, Virginia. Liquid and compressed oxygen, USP 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 (CFR), 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, manufacturing, processing, packing, storage, or holding, are not in conformance with GMP regulations.

The deviations observed include the following:

- Failure to establish and to document the accuracy and reproducibility of the test methods employed by the firm to assure conformance to final specifications for liquid oxygen, USP.
- Failure to test each vessel of liquid oxygen, USP, prior to release, for conformance to final product specifications for strength, identity, and quality.
- Failure to perform, at least, identity testing, prior to redistribution, of cryogenic home vessels that have been removed from service for maintenance or repair.
- Failure to perform adequate pre-fill, fill, and post-fill operations on each high pressure cylinder, and pre-fill operations on each cryogenic home vessel.

- **Failure to assure that each person engaged in the transfilling of medical gases has the education, training, or experience to enable that person to perform the assigned function.**
- **Failure to document that each significant step of the transfilling operation for each batch of oxygen, USP is completed. For example:**
  - a. **Transfillers were observed completing batch production and control records, prior to completion of each step.**
  - b. **Transfillers fail to document that each significant step of the operation has been completed for each cylinder, in that entries are made for only one cylinder per page of the batch production and control record.**
- **Batch production and control records are not reviewed for completeness and accuracy by the quality control unit on each day of transfilling.**
- **Failure to calibrate pressure gauges used in the oxygen, USP transfilling operation.**
- **Failure to establish written procedures describing the following:**
  - a. **The responsibilities and procedures applicable to the quality control unit.**
  - b. **A calibration program for thermometers and gauges.**
  - c. **Assay of product in cryogenic home vessels that have been out of service for maintenance or repair.**
  - d. **All calibration requirements and procedures for the [REDACTED] oxygen analyzer.**
  - e. **Pre-fill, fill, and post-fill operations performed on high pressure cylinders.**
- **Failure to identify each batch of oxygen, USP with a lot number to permit determination of the history of manufacture and control of the batch.**

At the conclusion of the inspection, Mr. Curtis Christiansen, Assistant Chief Executive Officer, was given a written list of inspectional observations (FDA-483) which was discussed with him. A copy was also mailed to you.

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 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

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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, Baltimore District, 900 Madison Avenue, Baltimore, Maryland 21201, to the attention of Nancy L. Rose, Acting Compliance Officer. Ms. Rose can be reached at (410) 962-4017, extension 138.

Sincerely,



Andrew Bonanno  
Acting Director, Baltimore District

cc: Maryland Board of Pharmacy  
4201 Patterson Avenue  
Baltimore, MD 21215-2299

Mr. Dennis Carroll  
Associate Regional Administrator  
Health Care Finance Administration  
Room 3100  
3535 Market Street  
Philadelphia, PA 19101 (purged)