



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: FEI 1000123024

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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) 962-3396  
FAX: (410) 962-2219

May 10, 2000

**WARNING LETTER**

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

Ms. Donna Sue Musick, President  
Home Care Equipment, Inc.  
231 West Main Street  
Lebanon, Virginia 24266

Dear Ms. Musick:

A Food and Drug Administration (FDA) inspection was conducted on April 12-13, 2000 at your medical gas manufacturing facility located in Lebanon, 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, as specified in 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, their manufacturing, processing, packing, storage, or holding, are not in conformance with GMP regulations.

The deviations observed include the following:

- Failure to adequately test each batch of Oxygen, U.S.P. for conformance to final specifications prior to release (i.e., failure to document the purity analysis for cylinders transfilled from 9/14/99 (Lot # 677) through 11/29/99 (Lot # 705) and to perform and/or document the calibration of the oxygen analyzer on 10/19/99, 1/17/00, 2/25/00, and 3/9/00).
- Failure to establish adequate written production and processing control procedures.
- Failure to perform and/or document the pressure reading during the transfilling of cylinders and the required post-fill checks.
- Failure to perform and/or document the review of batch production records by the quality control unit to determine compliance with all established, approved written procedures before release or distribution of a batch.
- Failure to perform and/or document the calibration of the thermometer used during transfilling operations.

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- Failure to adequately train employees responsible for transfilling to enable them to perform this assigned function.

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. The specific violations noted in this letter and on 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 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 being initiated by the FDA 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, 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,



Lee Bowers

Director, Baltimore District