



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Refer to: CFN 1125547

Public Health Service

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3396
FAX: (410) 962-2219

HF135

M23857

February 18, 1999

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. James Stimple, CEO
Health Facilities, Inc.
Davis Respiratory Care
909 Gorman Avenue
Elkins, West Virginia 26241

Dear Mr. Stimple:

A Food and Drug Administration (FDA) inspection was conducted on December 21 and 23, 1998 at your medical gas manufacturing facility located at 213 Main Street, Elkins, 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 (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 included the following:

- Failure to document and/or test finished Oxygen, U.S.P. for identity and strength.
- Failure to review batch production records prior to release of finished Oxygen, U.S.P.
- Failure to maintain adequate records and on one occasion document the fill and post-fill inspections conducted on each high-pressure cylinder used to manufacture Oxygen, U.S.P.
- Failure to establish written procedures describing such operations as a quality control unit, training, complaints, and recalls.
- Failure to establish a quality control unit.

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- Failure to document that each person engaged in the transfilling of compressed Oxygen, U.S.P. has the education, training, or experience to enable that person to perform their assigned function.

At the conclusion of the inspection, Mr. Robert M. Kerns, General Manager was presented with a written list of inspectional observations (FDA-483) which was discussed with him. A copy of the FDA-483 is enclosed for your reference.

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 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, 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,


Carl E. Draper
Acting Director, Baltimore District

Enclosure

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cc: West Virginia Department of Health & Human Resources
Building #3, Rm. 206, Capitol Complex
1900 Kanawha Boulevard, East
Charleston, West Virginia 25305