

HFI-35

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

PS
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CFN 1124684

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

October 23, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ms. Bonnie E. Dandrea
Chief Executive Officer
Valley Medical Equipment and Supply
1389 Saratoga Avenue
Star City, West Virginia 26505

Dear Ms. Dandrea:

The Food and Drug Administration (FDA) conducted an inspection of your Star City, West Virginia facility on October 3, 1997. During the inspection, deviations from the Current Good Manufacturing Practice Regulations (Title 21, Code of Federal Regulations (CFR), Parts 210 & 211) were observed. These deviations cause your Oxygen, U.S.P. to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act). The deviations observed include the following:

1. Failure to assay the filled high-pressure cylinders of Oxygen, U.S.P. for identity and strength prior to release.
2. Failure to perform adequate filling operations on each high-pressure cylinder filled.
3. Failure to establish written procedures for the production and process controls covering pre-fill, fill, and post-fill operations designed to assure that the drug product has the identity, strength, quality, and purity it purports or is represented to possess, and failure to have such written procedures approved by a quality control unit.

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4. Failure to establish adequate 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.
5. Failure to establish adequate written procedures designed to assure that correct labels, labeling, and packaging materials are used.
6. Failure to establish a quality control unit.

Our investigator found that several of your Oxygen, U.S.P. cylinders are not properly labeled, as the shoulders of several cylinders are gray in color. The Oxygen, U.S.P. is misbranded under Section 502(a) of the Act, as its labeling is false and misleading. The gray color on the compressed medical gas cylinders represents or purports that they contain Carbon Dioxide; however, each cylinder is labeled Oxygen, U.S.P. In addition, cylinders painted or labeled gray and green represent and identify a gas mixture of carbon dioxide and oxygen. We acknowledge that your firm removed from use and quarantined the misbranded cylinders at the close of the inspection.

The above listed 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 about 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 compressed medical gases guideline which discusses the applicability of the Current Good Manufacturing Practice Regulations to medical gas manufacturers.

You should notify this office in writing, within 15 working days of receipt of this letter, of specific steps you have 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.

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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, Ext. 14.

Sincerely,



Elaine Knowles Cole
Baltimore District Director

Enclosure

cc: West Virginia Board of Pharmacy
236 Capitol Street
Charleston, WV 25301

Bureau For Public Health
Office of Environmental Health Services
815 Quarrier Street, Suite 418
Charleston, WV 25301-2616