



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

M21907

RB 11/10/98

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

November 13, 1998

WARNING LETTER

Terry J. Stoural, Secretary
Treasurer
Home Health Medical Equipment, Inc.
2604 West Norfolk Avenue
Norfolk, NE 68701

KAN #99-003

Dear Mr. Stoural:

Recently inspections were made of your compressed medical oxygen transfilling operations located at the above address, and at 247 North Main Street, Ainsworth, Nebraska. These inspections were conducted on September 23 and October 6, 1998, respectively, by a Food and Drug Administration Investigator from this office who documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211). These deviations cause the medical oxygen transfilled at both locations to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations include, but are not limited to the following:

failure to document the training of employees in CGMP's and the transfilling of compressed medical oxygen [21 CFR 211.25(a)];

failure to follow written procedures designed to assure that the compressed medical gas has the identity and strength it purports or is represented to possess [21 CFR 211.100];

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failure to calibrate the Ceramatec OM-25A oxygen analyzer and to maintain calibration records [21 CFR 211.160(b)(4) and 21 CFR 211.194(d)];

failure to establish that the Ceramatec OM-25A oxygen analyzer will provide test results that are equivalent or superior to the official test procedure [21 CFR 211.165(e)];

failure to conduct release testing, i.e., identity and potency, on filled cylinders [21 CFR 211.165(a)];

failure to establish adequate batch production and control records of each batch of compressed medical oxygen produced, including documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished [21 CFR 211.188(b)];

failure to calibrate pressure and vacuum gauges and failure to use a thermometer during the cylinder filling process [21 CFR 211.68];

failure to establish procedures to assure that assigned lot numbers permit determination of the history of the manufacture and control of the batch [21 CFR 211.130(b)].

This letter is not intended to be an all-inclusive list of deficiencies at your facilities. It is your responsibility to ensure adherence to each requirement of the Act and regulations, at each medical gas facility you operate. We are enclosing a copy of the Form FDA 483 which was issued to Ms. DeVonne G. Lytle, Office Manager, at your Ainsworth, Ne facility.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your medical oxygen. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction.

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Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

Mary Wolyske
for

W. Michael Rogers
District Director
Kansas City District

Enclosure - Form FDA 483

cc: DeVonne G. Lytle, Office Manager
Home Health Medical Equipment, Inc.
247 North Main Street
Ainsworth, NE 69210