



9/11/00 RB m4148n

September 8, 2000

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

WARNING LETTER

KAN #2000-026

David H. Vellinga
Chief Executive Officer
Mercy Medical Center
1111 6th Avenue
Des Moines, IA 50314

Dear Mr. Vellinga:

Recently an inspection was made of your medical gas transfilling operation known as Mercy Home Respiratory Care, 1188 6th Avenue, Des Moines, Iowa. This inspection was conducted on August 14, 2000 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 gases transfilled at this location 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 routinely document the witnessing of testing by your Liquid Oxygen USP (LOX) supplier, of LOX for identity and purity. Since 3-1-99 there have been at least 18 Certificates of Analysis that have indicated testing was not witnessed.

Failure to establish and follow written procedures designed to assure that LOX and compressed medical oxygen has the identity and strength it purports or is represented to possess. Examples include 1) your "Policy for Liquid Oxygen/Compressed Gas..." does not address the handling of LOX received in your truck mounted vessel; 2) Your "Aluminum Cylinder Fill Procedure" is not being followed in that a checkmark is being used to document purity tests, rather than the actual values.

Failure to have a documented procedure describing the responsibilities of the quality control unit or personnel.

Failure to fully document the training of your employees in current good manufacturing practices (CGMPs) in the filling of LOX and compressed medical oxygen.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. We are enclosing a copy of the Form FDA 483 that was issued to Keith L. Wachter, Administrative Director, at the conclusion of the inspection.

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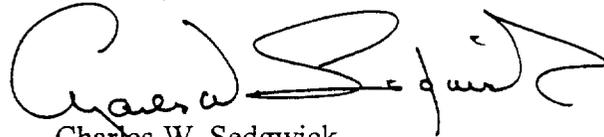
By copy of this letter, we are advising the Health Care Finance Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of state or federal law.

You should know that these serious violations 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 problems. 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.

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

Sincerely,



Charles W. Sedgwick
District Director
Kansas City District

Enclosure – Form FDA 483

cc: Jeannine K. Bowen
Respiratory Coordinator
Mercy Home Respiratory Care
1188 6th Avenue
Des Moines, IA 50314

CRP:jl