



“Certified/Return Receipt Requested”

September 23, 1998

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

Lucinda A. Bradley, President
Great Plains Regional Medical Center
601 West Leota
North Platte, NE 69101

Ref.# - KAN-98-025

Dear Ms. Bradley:

During an inspection of your medical liquid oxygen transfilling operation known as Great Plains Homecare Equipment, Inc., North Platte, Nebraska, conducted on August 27, 1998, a Food and Drug Administration Investigator from this office documented deviations from the Current Good Manufacturing Practice (CGMP) Regulations (Title 21, Code of Federal Regulations, Part 211) which cause your firm's liquid medical oxygen to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (Act).

Significant deviations to 21 CFR, Part 211 include, but are not limited to the following:

failure to routinely assay incoming liquid oxygen for identity prior to filling liquid home units, and failure to document the witnessing of liquid oxygen testing when picked up [21 CFR 211.165(a)];

failure to perform and document adequate prefill operations on each cryogenic home vessel, prior to filling [21 CFR 211.84(d)(3)];

failure to have a written procedure describing the responsibilities of the quality control unit [21 CFR 211.22(a)].

At the conclusion of the inspection Form FDA 483, Inspectional Observations, was prepared, issued to and discussed with Mr. Edward C. Erickson, General Manager. A copy of this form is included for your information.

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Great Plains Regional Medical Center

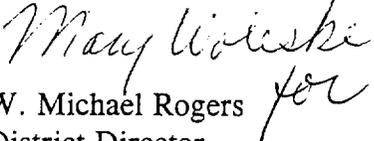
This letter is not intended to be an all-inclusive list of deficiencies at the stated facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such actions may include seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the specific steps that are being 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 Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,


W. Michael Rogers *for*
District Director
Kansas City District

Enclosure - Form FDA 483

cc: Edward C. Erickson, General Manager
Great Plains Homecare Equipment, Inc.
403 East "B" Street
North Platte, NE 69101