



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

February 24, 1998

**WARNING LETTER**

Daniel T. Sims, Owner/President  
Mobile Med + Care, Inc.  
10415 Lackman Road  
Overland Park, KS 66219

Ref.# - KAN-98-011

Dear Mr. Sims:

During an inspection of your medical liquid oxygen transfilling operation located at the above address, conducted on January 22 and 26, 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 [21 CFR 211.165(a)];

failure to establish the reliability of the supplier's certificate of analysis through appropriate validation of the supplier's test results, by conducting an audit of the supplier at least annually [21 CFR 211.84(d)(3)];

failure to calibrate the  Oxygen analyzer following manufacturers instructions in that there is no operations manual available [21 CFR 211.160(b)(4)];

failure to provide adequate documentation that the Oxygen being used as a calibration gas is a certified standard [21 CFR 211.160(b)(4)];

failure to maintain complete and accurate batch production records in that "Liquid Oxygen Fill Logs" are lacking documentation of supervisory review [21 CFR 211.188].

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.

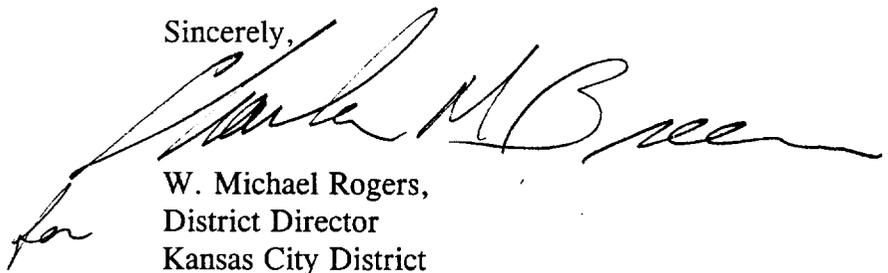
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory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

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 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,

A handwritten signature in black ink, appearing to read "W. Michael Rogers", is written over the typed name and title. The signature is fluid and cursive, with a long horizontal stroke at the end.

W. Michael Rogers,  
District Director  
Kansas City District