



DEPARTMENT OF HEALTH & HUMAN SERVICES

mason RB

RB 4/29/99

Certified/Return Receipt Requested

April 26, 1999

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**

Jeffrey W. Fort, President  
Red Oak Industrial Gas, Inc.  
306 3<sup>rd</sup> Street  
Red Oak, IA 51566

KAN #99-019

Dear Mr. Fort:

Recently an inspection was made of your liquid medical oxygen transfilling operation known as Carroll Industrial Gases, Inc., 734 East Highway 30, Carroll, Iowa. This inspection was conducted on March 23, 1999, 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 liquid medical oxygen 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 assay incoming liquid oxygen for identity prior to filling liquid home units [21 CFR 211.165(a)];
- failure to calibrate the Servomex 572 Oxygen analyzer following manufacturers instructions in the operations manual, and failure to maintain a record of calibration [21 CFR 211.160(b)(4) & 21 CFR 211.194(d)];
- failure to maintain complete and accurate batch production records in that documentation of supervisory review is missing, and documentation required by your SOP 2.040 is missing [21 CFR 211.188];
- failure to use a lot numbering system which allows complete traceability of the product (21 CFR 211.130(c)).

Page 2

April 26, 1999

Red Oak Industrial Gas, Inc.

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 John W. Pontow, Branch Manager, at the conclusion of the inspection.

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 liquid 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.

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

Sincerely,



W. Michael Rogers  
District Director  
Kansas City District

Enclosure - Form FDA 483

cc: John W. Pontow, Branch Manager  
Carroll Industrial Gases, Inc.  
734 East Highway 30  
Carroll, IA 51401