



Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
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February 7, 2000

**WARNING LETTER**  
**CIN-WL-00-1580**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Mr. Fred L. Jackson, CEO  
Ashland Hospital Corporation  
2201 Lexington Avenue  
Ashland, KY 41101

Dear Mr. Jackson:

The Food and Drug Administration conducted an inspection of your liquid and gaseous oxygen USP transfilling facility, King's Daughters Home Medical Equipment and Supplies located at 8985 Ohio River Road, Wheelersburg, Ohio 45694 on January 25 and 26, 2000. Our investigator documented significant deviations from the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals (Title 21 Code of Federal Regulations [CFR] Parts 210 and 211). These deviations cause your drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act).

The deviations documented during the inspection included:

1. The Oxygen Analyzer is not calibrated each day of use.
2. A designated Quality Control Unit has not been established.
3. Failure to maintain complete liquid and gaseous transfilling records as follows:
  - a) Eleven gaseous transfill records showed no results of analysis before the cylinders were shipped
  - b) The pre-fill inspections for liquid oxygen tanks were not documented on the transfill records.
  - c) The person doing the transfilling and reviewing the transfill record was the same person in some cases.
4. The Standard Operating Procedures do not contain information concerning the generation of tank lot numbers.
5. There was no documentation that the transfilling pressure gauges, vacuum gauge and the thermometer were calibrated.

It was also noted that your firm is using an industrial oxygen label on the transfilled cylinders instead of an Oxygen USP label. This causes the Oxygen USP cylinders to be misbranded under Section 502(a) of the Act.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all requirements of the Act and regulations promulgated thereunder are being met.

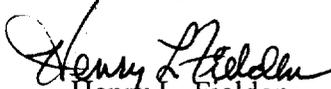
Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this into account when considering the award of contracts. By copy of this letter, we are advising the Health Care Facility Administration (HCFA) that our inspection of your firm revealed significant 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 take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by FDA without further notice. These actions include seizure and injunction.

Please notify this office within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the noted violations including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to The Food and Drug Administration, Compliance Branch, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Lawrence E. Boyd, Compliance Officer.

Sincerely,

  
Henry L. Fielden  
District Director  
Cincinnati District

cc: Rodney D. Mullins  
Department Manager  
King's Daughters Home Medical Equipment & Supply  
8985 Ohio River Road  
Wheelersburg, OH 45694

Health Care Finance Administration  
Chief Carrier Operations Branch  
105 West Adams, 15<sup>th</sup> Floor  
Chicago, IL 60603-6201