



DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

**PURGED** *PK*Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

October 2, 1997

cc: HFI-35/FOI Staff  
DWA**WARNING LETTER****CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 98 - 1

Herman Knieling  
President  
Airgas, Inc.  
Five Radnor Corporation Center, Suite 550  
100 Matsford Road  
Radnor, Pennsylvania 19087

Dear Mr. Knieling:

During our recent inspection of your Wisconsin Airgas medical oxygen transfiller operation on September 16 and 18, 1997, located in Green Bay, WI, our investigator found serious violations of the Current Good Manufacturing Practices (GMPs) for Finished Pharmaceuticals, Title 21, Code of Federal Regulations, Part 211 (21 CFR 211). Oxygen is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act). Your transfilled oxygen is adulterated within the meaning of Section 501(a)(2)(B) of the Act.

The violations observed during our inspection include but are not limited to the following:

1. Failure to maintain strict control over labeling issued. No approved master label for medical oxygen in GP-45 cryogenic vessels is available to carefully compare incoming labels for identity and conformity.

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2. Failure to maintain an accurate label control record. On September 16, 1997, the balance of released label stock read [REDACTED] when in fact there were approximately [REDACTED] such labels.
3. Failure to perform adequate label checks on GP-45 cryogenic vessels. Obsolete and outdated labels are not being destroyed as four released vessels on hand contained obsolete labels.
4. Failure to follow the SOP ensuring proper performance of your equipment. The filter element of your [REDACTED] Oxygen Purity Analyzer is not checked monthly for dirt and moisture, and failure to maintain a Filter Check Log as described in your SOP.
5. Failure to calibrate the vacuum gauge used on the medical oxygen transfilling line. This deviates from your SOP on calibration.

In addition, your transfilled oxygen is misbranded within the meaning of 502(f)(1) of the Act in that its label fails to bear adequate directions for use and it is further misbranded within the meaning of 503(b)(4) of the Act in that its label fails to bear the statement, "Caution: Federal law prohibits dispensing without a prescription."

The above indication of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so 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. Possible actions include seizure and or injunction. This is official notification that FDA expects all your locations to be in compliance.

Our investigator noted in his Establishment Inspection Report that during the discussion of the FDA-483, Regional Manager David Bloomer stated that a number of corrections to problems cited during the inspection had already been made.

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You should notify this office in writing, within 15 working days of receipt of this letter, of 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 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 Compliance Officer Carrie A. Hoffman at the address indicated on the letterhead.

Sincerely,

  
James A. Rahto  
Director  
Minneapolis District

CAH/ccl

xc: Ronald Beebe  
President  
Michigan Airgas Inc.  
311 Columbus Ave.  
Bay City, MI 48708

David J. Bloomer  
Regional Manager  
Wisconsin Airgas  
1831 East Mason  
Green Bay, WI 54302