



DEPARTMENT OF HEALTH & HUMAN SERVICES

cc HFI-35/FOI Staff
DWA

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URGENT

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

February 4, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97-32

G. Edwin Howe
President
Aurora Health Care Corporation
3000 West Montana Avenue
Milwaukee, Wisconsin 53215

Dear Mr. Howe:

During our January 13-14, 1997, inspection of your medical oxygen manufacturing facility located in West Allis, WI, our investigators documented serious violations of Title 21, Code of Federal Regulations Parts 210 and 211 (CFR), Good Manufacturing Practices (GMP). Medical oxygen is a drug withing the meaning of Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act). Drugs manufactured in a facility operating out of conformance with GMP are adulterated within the meaning of Section 501(a)(2)(B) of the Act.

Deviations from GMP which were observed include but are not limited to the following:

1. An identity test is not performed on incoming oxygen for which a Certificate of Analysis (C of A) is received from the supplier.
2. Home units are not tested for identity prior to being returned to service after repair.

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3. Certificates of Analysis are not always received from the supplier prior to transfilling.
4. Incoming oxygen is not tested for purity and/or identity when a C of A is not received.
5. C of A accompanying a lot of product are not checked to verify they represent the lot received. Several lots of oxygen were found to have a C of A from the wrong lot.
6. Production records are not checked by a second individual.
7. Standard Operating Procedures at the firm have no approving signatures, and the SOPs are not being followed.
8. The reliability of the C of A from suppliers is not established by validation of the test results at appropriate intervals, i.e., at least annually.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. On January 14, 1997, Form FDA-483, Inspectional Observations, was issued to Mr. Mark P. Hilgart, Vice President of Operations, at this facility. It is your responsibility to ensure adherence with each requirement of the Good Manufacturing Practice 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. Additionally, pending Antibiotic Form 6, NDA, ANDA, or export approval requests may not be approved until the above violations are corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

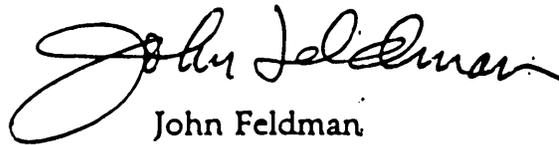
Please notify this office within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your reply should be sent to Compliance Officer Lawrence R. Murphy of the Minneapolis District Office at the address indicated on the letterhead.

Sincerely yours,



John Feldman
Director
Minneapolis District

LRM/ccl

xc: Sue J. Ela
President
Visiting Nurses Associates
Aurora Home Medical Services
11333 West National Avenue
West Allis, WI 53227