



*Handwritten initials/signature*

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

**PURGED** *RTK*

cc: HFI-35/FOI Staff  
DWA

July 29, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 56

Gordon M. Derzon  
Superintendent  
University of Wisconsin Hospital  
600 Highland Avenue, H4/810  
Madison, Wisconsin 53705

Dear Mr. Derzon:

Our recent inspection of your Oxygen USP transfilling operations at your Regional Services facility at 810 University Bay Drive, Madison, WI, revealed operations which are significant deviations from Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)]. Oxygen is a drug within the meaning of Section 201(g)(1) of the Federal Food, Drug and Cosmetic Act (the Act).

Your medical oxygen is adulterated within the meaning of Section 510(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of this product are not in conformance with 21 CFR 210 and 211. Deviations from CGMPs which were observed include, but are not limited to, the following:

1. Failure to assay the filled stand tanks or the trucks transfilled with oxygen for identity and strength prior to distribution.

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2. Failure to maintain complete records of the periodic calibration and maintenance of the oxygen analyzer and perform maintenance operations as required by the analyzer.
3. Failure to have an adequate procedure which describes all necessary steps for testing the identity and strength.

The above list of violations is not intended to be an all-inclusive list of deficiencies at your facility. Please refer to the form FDA-483, Inspectional Observations, that was issued to Mr. Daniel J. Shea, Respiratory Therapy Supervisor, on June 11, 1997, at the conclusion of the inspection. It is your responsibility to ensure adherence to each requirement of the Act and associated regulations. Failure to correct these deviations may result in regulatory action such as seizure or injunction without further notice. 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.

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 the requested time frame, you must promptly inform this office of the reason for the delay and the time when each violation will be corrected.

Your reply should be addressed to Acting Compliance Officer Rhonda L. Mecl at the address indicated on the letterhead. Ms. Mecl may be reached at (612) 334-4100 ext. 159.

Sincerely,



Edwin S. Dee  
Acting Director  
Minneapolis District

RLM/ccl

xc: Richard Reynolds  
Director of Management, Engineering & Regional Services  
Regional Services Department  
University of Wisconsin Hospital  
600 Highland Avenue, H4/828  
Madison, WI 53705

Daniel J. Shea  
Respiratory Therapy Supervisor  
Regional Services Department  
University of Wisconsin Hospital  
810 University Bay Drive  
Madison, WI 53705