

**PURGED**

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

January 13, 1997

cc: HFI-35/FOI Staff  
DWA

**WARNING LETTER**

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

Refer to MIN 97-26

Daniel L. Haile  
President,  
Lakeshore Respiratory Therapy Care Services S.C.  
621 York Street  
Manitowoc, Wisconsin 54220

Dear Mr. Haile:

On December 18, 1996, Investigator John P. Hermann of the Food and Drug Administration conducted an inspection of your liquid oxygen USP transfilling firm. The investigator found your firm to be operating under significant deviations from the 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 USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (the Act).

Your medical gases are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product are not in conformance with 21 CFR 210 and 211. Violations encountered during the FDA inspection include, but are not limited to, the following:

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- Your firm does not perform adequate tests for identity and strength on each batch of transfilled oxygen USP, i.e., failure to test the incoming oxygen USP by one of the following methods: (1) have an individual who has received training specific to the analytical methodology witness the testing; (2) rely on a valid Certificate of Analysis from the supplier along with an identity test on each fill of the vehicle-mounted vessel with Liquid Oxygen (LOX); or (3) perform the full USP testing [21 CFR 211.165(a)]. Your firm should have a written procedure describing performance and documentation of the testing. Your firm was sent a Warning Letter on November 23, 1993, citing your lack of records for testing the incoming bulk LOX for strength and identity and lacking an acceptable Certificate of Analysis. Although you are now receiving bulk LOX with a Certificate of Analysis, it bears repeating that you must perform an identification test on the oxygen if you wish to use this testing option.
- Upon receiving cryogenic vessels back from repair or maintenance, they are not checked for at least the identity of their contents prior to redistribution [21 CFR 211.165(a)]. As previously mentioned, your written procedures should reflect the requirement to perform and document this testing.

I enclose a copy of a speech entitled "Fresh Air '96" delivered at the New Orleans Medical Gases GMP Workshop held in Baton Rouge, LA, on April 23, 1996, by FDA National Expert Duane Sylvia. Please note that the testing of incoming bulk liquid oxygen is addressed on pages 4 and 5.

The above violations are not meant to be an all-inclusive list of deficiencies in your operation. As president, the most responsible individual at Lakeshore Respiratory Therapy Care Services S.C., it is ultimately your responsibility to ensure that the oxygen USP from your facility in Manitowoc, WI, is transfilled in compliance with all applicable statutes enforced by the FDA. 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.

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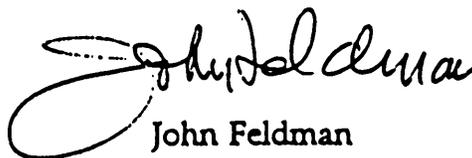
As a drug manufacturer you are responsible to ensure that the appropriate changes are made to your operation to bring your products into compliance with the law.

You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action including seizure and/or injunction without further notice.

We request that you notify this office in writing within 15 working days of your receipt of this letter of the measures you intend to take to correct the cited violations. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612) 334-4100 ext. 156.

Sincerely yours,



John Feldman  
Director  
Minneapolis District

HEM/ccl

Enclosures: "Fresh Air '96"  
FDA-483, 12/18/96