



August 11, 1999

Chicago District  
300 S. Riverside Plaza, Suite 550 South  
Chicago, Illinois 60606  
Telephone: 312-353-5863

WARNING LETTER  
CHI-30-99

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Emmanuel J. Likou  
Chairman, Board of Directors  
Total Respiratory Services and Medical  
Equipment, Inc.  
39W981 Duchesne Drive  
West Dundee, Illinois 60118

Dear Mr. Likou:

During an inspection of your facility, located on 1554 Todd Farm Drive, Elgin, Illinois, on July 8 & 12, 1999, our investigator Yvonne E. Lozano, determined that your firm manufactures liquid Oxygen, U.S.P., and distributes oxygen gas in high pressure cylinders. These medical gas products are drugs as defined by Section 210(g) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that your liquid Oxygen, U.S.P., and your high-pressure compressed oxygen are adulterated under the Act.

Your Oxygen, U.S.P., and high-pressure compressed oxygen are adulterated under Section 501(a)(2)(B) of the Act in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with the Current Good Manufacturing Practice Regulations (CGMPs) for drugs as specified in Title 21, Code of Federal Regulations, Parts 210 & 211, as follows:

1. Failure to perform identity tests on all lots of liquid oxygen that are filled into the vehicle mounted vessel before dispensing into cryogenic home vessels.
2. Failure to have a written procedure for the filling of the vehicle mounted tank with liquid oxygen delivered by [REDACTED]
3. Failure to have a written procedure for the filling of cryogenic home vessels by the driver from the vehicle mounted tank.
4. Failure to have documentation showing that specific tests (external, valve, contents gauge and label inspection) are performed on cryogenic home vessels when they are filled at a patient's home.

5. Failure to document that all employees conducting liquid oxygen and oxygen gas handling and filling operations have been properly trained.
6. Failure to ensure that all cylinders containing Oxygen, U.S.P., have product labels.
7. Failure to have written procedures for recall of defective product.
8. Failure to ensure that all batch records are complete and include documentation for all significant steps in the manufacturing process.

These findings were discussed with Mr. Alan P. Kirk, operations manager, on July 12, 1999, when he was given the form FDA-483, List of Observations, by Ms. Lozano.

The above does not represent an all-inclusive listing of the violations noted during the inspection of your firm. It is your responsibility to assure adherence with each requirement of the CGMPs regulations. Federal Agencies are advised of the issuance of all warning letters concerning drugs and devices so that 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, such as seizure and/or injunction, without further notice.

We have enclosed the latest copy of a speech by our National Expert, Mr. Duane Sylvia, entitled "Fresh Air '98 – A Look at FDA's Medical Gas Requirements." The contents of this speech should assist you in understanding your responsibilities as a medical gas manufacturer.

If you wish to obtain a copy of the Act [DHHS Publication No. (FDA) 93-1051] or 21 CFR Parts 200 to 299 (SN 869-026-00071-9), you should contact the Superintendent of Documents, Attention: New Orders, P.O. Box 371954, Pittsburgh, PA 15250-7954. Charge orders may be telephoned to the GPO Order Desk at (202) 512-1800 from 8:00 a.m. to 4:00 p.m. Eastern Time, Monday through Friday, or faxed to (202) 512-2233. You can also obtain these publications in Chicago by calling the Government Bookstore at (312) 353-5133. The Act costs approximately \$20.00 and the CFR is approximately \$9.00.

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You should notify this office in writing within 15 working days of receipt of this letter regarding 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 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

Your written response should be directed to the attention of Richard Harrison, Director, Compliance Branch.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

Enclosures: Copy of "Fresh Air '98"  
FDA-483