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28 October 1997

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

WARNING LETTER BUF 98-1

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

Patrick M. Egan, President/CEO
American Access & Mobility Inc.
dba Mercy Medical Equipment & Oxygen Company
2170 Union Road
West Seneca, NY 14224

Dear Mr. Egan:

Inspection of your medical oxygen repacking facility at 2170 Union Road, West Seneca, NY, was performed 15-17, 21 and 22 October 1997 by Food and Drug Administration Engineer Kim M. Downing. The inspection revealed Oxygen USP repacked at your facility is adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act (the Act) because the controls used for its manufacture, processing, packing or holding are not in conformance with current good manufacturing practice (CGMP) regulations.

The inspection revealed numerous deviations from the CGMP regulations (Title 21, Code of Federal Regulations, Parts 210 and 211). These deviations were included in the FDA-483 Inspectional Observations issued to you at the conclusion of the inspection and discussed with your employees during the inspection. The most significant deviations noted relate to your failure to adequately test the oxygen and to document the testing performed, prior to release of the finished product. These deviations include the following:

- **A valid certificate of analysis for incoming bulk shipments of oxygen is not obtained, nor is full compendial testing per the United States Pharmacopeia performed on incoming oxygen [21 CFR 211.84(d)(2)].** Your bulk oxygen receipt documentation does not reflect the purity of the oxygen received on a lot by lot basis and if a valid certificate of analysis is not received, full compendial testing on the incoming oxygen would be required.
- **Failure to establish scientifically sound and appropriate test procedures for the assay of Oxygen gas USP [21 CFR 211.160(b)].** You have not established test specifications for incoming Oxygen USP or for release of repacked Oxygen USP, and had no written instructions or test procedures for the [REDACTED] used to test finished product. You have not established and documented the accuracy, sensitivity, specificity, and reproducibility of the test method for oxygen.



- **Failure to calibrate instruments** [REDACTED] **and gauges (vacuum, oxygen pressure) at suitable intervals in accordance with an established written program [21 CFR 211.160(b)(4)].** You did not have the high purity Nitrogen required to calibrate the “zero” on the meter, and you did not have a certificate of analysis establishing high purity of the oxygen used to calibrate the analyzer. Employees responsible were not knowledgeable about the calibration of the analyzer or the gauges.

In addition, the following deviations were also noted:

- **Failure to perform adequate prefill operations on each high pressure cylinder prior to filling [21 CFR 211.84(d)(3)].** Your procedures do not describe the specific requirements for the odor test and the visual checks performed.

- **Failure to have complete written procedures for production and process control designed to assure the Oxygen USP product has the identity, strength, quality and purity it purports or is represented to possess [21 CFR 211.100(a)].**

- **Failure to establish written procedures designed to assure correct labels and labeling are used, including identification of the product with a lot or control number that permits a determination of the history of the manufacturing and control of the batch [21 CFR 211.130(b)].** Your lot numbering system does not allow traceability back to all of the supply oxygen used in the manufacture of the finished product lot.

- **Failure to establish adequate batch production and control records for each batch of drug product produced, including documentation of each significant step in the manufacture, processing, packing, or holding of the batch [21 CFR 211.188(b)].** Your records were found to inaccurately indicate completion of the labeling operation, and failed to indicate the size of the containers filled.

- **Personnel responsible for the repacking and testing of compressed Oxygen USP lack the education, training, and experience needed to perform their assigned functions in such a manner as to provide assurance the drug product has the safety, identity, strength, quality, and purity it purports or is represented to possess [21 CFR 211.25(a) and (b)].** In addition, employees involved in witnessing the supplier’s testing of Liquid Oxygen USP also lack the required education, training and experience necessary to assure the testing is performed appropriately. ↘

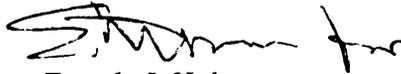
It is your responsibility to assure all drugs manufactured and distributed by your firm meet the requirements of the Act, and regulations promulgated thereunder. You should take prompt action to correct this violation, and all other violations existing at your firm, and to establish procedures

whereby such violations will not recur. Failure to achieve prompt correction may result in regulatory action - **without further notice**. This action may include, but is not limited to, seizure and/or injunction.

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. By copy of this letter, we are specifically advising the Health Care Financing Administration (HCFA) that our inspection of your firm revealed significant deviations from the Act. They may elect to defer or discontinue payment for any health care product in violation of State and Federal law.

Please notify this office in writing, within fifteen days, of the specific steps you have taken to correct the noted violations and to prevent a recurrence of similar violations. Your response should be directed to James M. Kewley, Team Leader, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "Brenda J. Holman".

Brenda J. Holman
District Director

Attachments: -Copy FDA-483 Inspectional Observations

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