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

21 November 1996

WARNING LETTER BUF 97-6

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

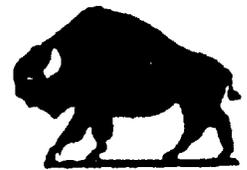
William W. Cramer, President and Owner
Albany Edison Oxygen Co., Inc.
2005 Central Avenue
Albany, New York 12205

Dear Mr. Cramer:

Inspection of your medical gas repacking facility at 2005 Central Avenue, Albany, New York, was performed 28 October and 1, 7 and 8 November 1996 by Food and Drug Administration Investigator Denise L. Terzian. The inspection revealed Oxygen U.S.P. 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), some of which remain uncorrected from previous inspections of your facility. These deviations were included in the FDA-483 Inspectional Observations issued at the conclusion of the inspection, and/or discussed with you 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. These include the following:

- A specific identity test is not performed on either the incoming bulk oxygen "or" the first cylinder repacked after each new shipment of bulk oxygen is added to the storage tank [21 CFR 211.84]. Acceptable methods of performing this test include, but are not limited to, use of a carbon dioxide detector tube with the Orsat buret test, or by using a properly calibrated hand-held analyzer;
- Your records do not include data (purity result) from the Orsat buret purity test reportedly performed on one cylinder from each manifold filling [21 CFR 211.194(a)(4) and (a)(6)];



- Documentation received with incoming shipments of bulk oxygen does not specify the oxygen was produced by the air liquefaction process, nor do you have on file documentation from the supplier stating the oxygen received is produced by the air liquefaction process. In lieu of such documentation, you are required to test for identity, carbon dioxide and carbon monoxide. Such testing is not being performed [21 CFR 211.84];
- Written procedures are not followed for evaluation of the buret used for purity testing after new solution has been added [21 CFR 211.160]; the procedure requires a minimum of three separate analyses after the test solution has been replaced, prior to acceptance of data;
- Preparation of test solutions used to perform the Orsat buret purity test is not documented [21 CFR 211.194];
- Written procedures do not address cleaning of the buret prior to performing the Orsat buret purity test [21 CFR 211.182]; On 11/1/96 the purity test could not be adequately performed because of a blue/white residue inside the buret.

Other CGMP deviations noted include the following:

- Failure to identify repacked oxygen cylinders with a unique lot or control number for each manifold filling [21 CFR 211.130(c)]; Each manifold filling represents a separate batch; however, multiple manifold fillings on the same day are being assigned the same lot number;
- Batch production records are inadequate because they fail to include the filling temperature and the filling or settled pressure of the cylinders [21 CFR 211.188(b), and fail to include the results of the pre-fill and post-fill cylinder inspections [21 CFR 211.100(b)];
- A signed and dated copy of the current approved labels is not maintained [21 CFR 211.186(b)(8)];
- Failure to pull an adequate vacuum on cylinders prior to filling [21 CFR 211.94(c)]; the cylinders are not being evacuated to 25 inches of mercury or greater; written procedures are inadequate because they do not require evacuation to 25 inches of mercury or greater;

- Failure to calibrate the thermometers and vacuum gauge at suitable intervals [21 CFR 211.160(b)(4)]; your records indicate the thermometers used in the repacking operation have not been calibrated in over a year; there were no records to indicate the vacuum gauge has ever been calibrated;
- Failure to have written procedures for control and reconciliation of labels [21 CFR 211.125]; controls and reconciliation procedures in use were deemed adequate, but written procedures were lacking;
- Written procedures for labeling filled cylinders are not being followed in that the labeling is being applied after the cylinders are removed from the manifold [21 CFR 211.130];
- Failure to perform leak testing of each filled cylinder *after removal from the manifold* [21 CFR 211.165(a)].

You should take prompt action to correct this violation and establish procedures whereby such violations will not recur. Failure to achieve prompt corrections may result in regulatory action - without further notice. This may include seizure and/or injunction.

Federal agencies are advised of the issuance of all Warning Letters about drugs and devices so they may take this information into account when considering the awarding 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 or Federal law.

If, after reviewing this Warning Letter and the COMPRESSED MEDICAL GASES GUIDELINE (copy attached), you still have questions regarding acceptable methods for complying with these requirements, you may contact James M. Kewley at our Buffalo office (716/551-4461, Ext. 3128).

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,



E. Pitt Smith
District Director

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Attachments: -Compressed Medical Gases Guideline
-Fresh Air '96 - A Look At FDA's Medical Gas Requirements