



DEPARTMENT OF HEALTH & HUMAN SERVICES

MA4267  
New York District

Food & Drug Administration  
300 Pearl Street, Suite 100  
Buffalo, NY 14202

February 24, 1999

**WARNING LETTER NYK 1999-32**

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

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

Dear Mr. Cramer:

An inspection of your medical oxygen repacking facility at 2005 Central Avenue, Albany, NY, was performed January 6 & 8, 1999, by Food and Drug Administration Investigator Michael G. Sinkevich. 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 deviations from the CGMP regulations (Title 21, Code of Federal Regulations, Parts 210 and 211), as follows:

- Records maintained do not indicate that identity testing was performed prior to release of [REDACTED] batches of Compressed Oxygen U.S.P. transfilled between 11/4/98 and 1/6/99 (21 CFR 211.194);
- Failure to establish written procedures describing in sufficient detail the test procedures and requirements for the receipt, transfilling and release of medical grade liquid and compressed Oxygen U.S.P. [21 CFR 211.100, 211.80 and 211.160(b)].

We received your correspondence of 1/12/99 in which you respond to the inspectional observations. This response is inadequate because it does not address corrective action for the lack of written procedures identified in FDA-483 observation 2.

Albany Edison Oxygen Company, Inc.  
Page 2

Your firm is required to establish and follow detailed written procedures that are specific to the operations of your facility. These procedures must cover all aspects of your medical oxygen repacking operations, including laboratory controls. Such laboratory controls must include the establishment of scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that components (such as bulk Oxygen U.S.P. received), drug product containers, in-process materials, labeling and finished drug products (transfilled Oxygen U.S.P.) conform to appropriate standards of identity, strength, quality, and purity. Records maintained must include complete data derived from all tests, including but not limited to, assay, identity and odor tests (21 CFR 211.194).

This is not the first time we have found your firm to be out of compliance with the requirements of the CGMP regulations. Previous inspections of your facility have found a variety of CGMP deviations related to your Oxygen U.S.P. transfilling operations. Our inspections have found that your previous promises of corrective action have not resulted in lasting correction.

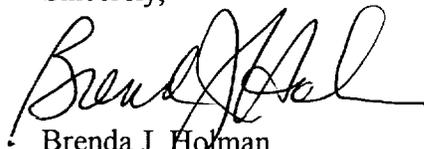
You should take prompt action to correct this violation and to establish procedures whereby such violations will not recur. Failure to achieve prompt corrections may result in regulatory action - without further notice. This may include seizure and/or injunction.

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, Compliance Officer, at the above address.

Sincerely,

  
Brenda J. Holman  
District Director

Attached: Compressed Medical Gases Guideline  
Fresh Air 98 - A look At FDA's Medical Gas Requirements