



Telephone (973) 526-6008

Food and Drug Administration  
Waterview Corporate Center  
10 Waterview Blvd., 3rd Floor  
Parsippany, NJ 07054

**WARNING LETTER**

**Certified Mail  
Return Receipt Requested**

File # 99-NWJ-10

January 20, 1999

Richard Lerner  
President  
Allcare Medical  
2590 Route 516  
Old Bridge, NJ 08857

Dear Mr. Lerner:

During an inspection of your oxygen repackaging facility firm, Galloping Hill Surgical, 1350 Galloping Hill Road, Union, NJ 07083, on November 24-30, 1998, our investigator documented deviations from Current Good Manufacturing Practices for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211). These deviations cause your drug product, Oxygen, USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug and Cosmetic Act.

Those deviations included:

- Failure to perform identity and purity testing on repackaged Oxygen, USP lots or individual cylinders [21 CFR 211.165]. Specifically, you do not assay at least one cylinder per filling sequence for identity and purity prior to release for distribution.
- Failure to calibrate the paramagnetic oxygen analyzer before use in testing the Oxygen, USP for identity and purity [21 CFR 211.160(b)(4)]. Calibration is necessary to maintain the safety, identity, quality and purity of the Oxygen, USP.
- Failure to perform adequate prefill operations on each cylinder filled with Oxygen, USP [21 CFR 211.84(d)(3)]. Specifically, you maintain no documentation of periodic calibrations of the vacuum device used to evacuate existing gas prior to filling.
- Failure to designate each filling sequence as a separate lot or batch for recordings of proper history of each batch [21 CFR 211.130(c)]. Each filling sequence must be identified as a

unique lot or batch and drug containers of that lot or batch must be affixed with a label identifying the appropriate lot number.

- Failure to document the temperature at which cylinders are filled [21 CFR 211.188(b)(5)]. This is an in-process control necessary to determine the appropriate fill pressure.
- Failure to review the production record for batches of Oxygen, USP transfilled on November 2, 1998, prior to their release for distribution [21 CFR 211.192].
- Failure to establish written procedures to assure that Oxygen, USP has the identity and purity it purports or is represented by labeling to possess [21 CFR 211.100(a) and 21 CFR 211.198]. Specifically, there are no written procedures for equipment maintenance and calibration of the thermometer, manifold pressure gauge, or vacuum pressure gauge; receipt and storage of T-type cylinders (components); and training of personnel in Current Good Manufacturing Practices.

You were previously informed of the requirements to test for purity and identity, to assign lot numbers, and establish standard operating procedures through a FDA-483 issued to your firm, Allcare Medical, on March 6, 1998.

The above deviations are not intended to be an all-inclusive list of violations. As a repackager of drug products for human use, you are responsible for assuring that your overall operation and the product you distribute are in compliance with the law.

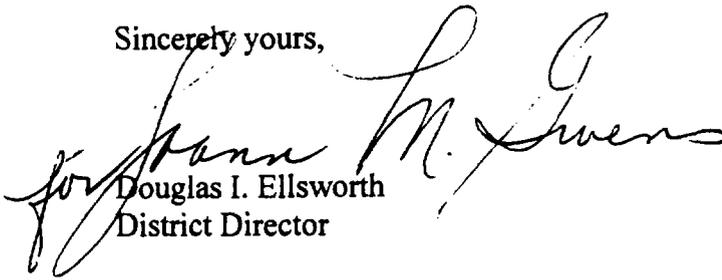
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

You should notify this office in writing, within 15 working days upon receipt of this letter, of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

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

Your reply should be directed to the Food and Drug Administration, Attention: Kirk D. Sooter, Compliance Officer, at the address and telephone number above.

Sincerely yours,

  
Douglas I. Ellsworth  
District Director

cc: Mr. Edwin L. Dillard  
Director of Operations  
Gallop Hill Surgical  
1350 Gallop Hill Road  
Union, NJ 07083

Beneficiary Services and Providers Branch Chief for New Jersey  
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