

HFF-35



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

102107W

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

Telephone (973) 526-6008

WARNING LETTER

**Certified Mail  
Return Receipt Requested**

File # 99-NWJ-01

October 5, 1998

Claire Liebenstein  
President  
Action Industrial Distributor  
26 Industrial Drive  
West Milford, NJ 07480

REVIEWED KIS 10/09/98  
DATE

Dear Ms. Liebenstein:

During an inspection of your oxygen repackaging facility on September 15 and 17, 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 uninterrupted filling sequence for identity and purity prior to release for distribution.
- Failure to assign a coding system to lots or batches of cylinders of Oxygen, USP transfilled. [21 CFR 211.196].
- Failure to properly calibrate the pressure gauge and vacuum gauge on the filling manifold [21 CFR 211.67(a)]. Specifically, those two devices require regular calibration to maintain the safety, identity, strength, quality and/or 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 evacuation of existing gas and interior cylinder cleanliness prior to filling.

- Failure to prepare and maintain batch production and control records for each batch or lot of Oxygen, USP transfilled, including complete information relating to the production and control of that batch or lot [21 CFR 211.188].
- 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, storage, finished product distribution, complaint handling, recall initiation and effectiveness operations, and training in Current Good Manufacturing Practices.
- Failure of the person conducting the repackaging of Oxygen, USP to demonstrate education, training and experience, or any combination thereof, that would enable the person to perform the assigned functions (i.e., CGMP training) [21 CFR 211.25(a)].
- Failure to annually register your business establishment for the past two calendar years [21 CFR 207.21(a)].

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.

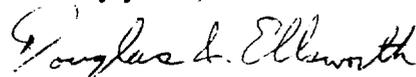
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

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 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