



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region

112105N

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

Telephone (973) 526-6008

HFI-35

WARNING LETTER

**Certified Mail
Return Receipt Requested**

File # 98-NWJ-39

October 2, 1998

GiGi Cabatu
President and Owner
G & G Medical and Oxygen
4701 Broadway Avenue
Union City, NJ 07087

RELEASE

REVIEWED BY KDS ¹⁰⁰⁵ 9/10/09/98
C.O.

Dear Ms. Cabatu:

During an inspection of your oxygen repackaging facility on September 14-17, 1998, our investigators 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 test each lot of bulk oxygen to determine conformance with appropriate specifications for identity and strength [21 CFR 84(d)(2)]. Specifically, you do not test each lot or individual cylinder of bulk oxygen received from your supplier for identity and strength nor do you maintain certificates of analysis indicating the identity and purity of bulk oxygen from your supplier.
- Failure to properly calibrate the oxygen analyzer used for the assay of Oxygen, USP [21 CFR 211.160(b)(4), 21 CFR 211.68(a) and 21 CFR 211.194(b)]. Specifically, that you did not have the high purity nitrogen and oxygen standards required to "zero" and "span" calibrate correctly. Also, there was no documentation indicating the analyzer had ever been calibrated. The oxygen analyzer manufacturer's instructions require periodic calibration.

- 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.
- The outdoor structure for your oxygen repackaging operation is unsuitable to facilitate proper operations [21 CFR 211.42(a)]. Specifically, the filling and testing of Oxygen, USP in an outdoor environment, where temperature and humidity conditions are not controllable, are not in compliance with current industry practices or Agency expectations. Filling and testing oxygen in an uncontrollable environment introduces potential problems such as fill volume and purity accuracy. Please consult the Fresh Air '97 document given to you by our investigators with respect to this issue.
- 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 repackaging, testing, equipment maintenance and calibration, bulk receiving, storage, finished product distribution, complaint handling and recall effectiveness operations.
- 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 register your business establishment and list your Oxygen, USP drug product with the Agency [21 CFR 207.20 and 207.21].

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.

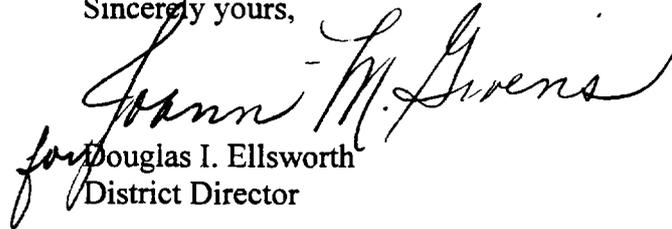
You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

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,

A handwritten signature in cursive script, appearing to read "Douglas I. Ellsworth". The signature is written in black ink and is positioned above the printed name and title.

Douglas I. Ellsworth
District Director