



Telephone (973) 526-6010

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

October 5, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Cynthia Hartshorne
President
Alpha Compressed Gases
716 New Brunswick Avenue
Alpha, New Jersey 08865

File No. 00-NWJ-01

Dear Ms. Hartshorne:

During the September 1, 1999 inspection of your medical oxygen repacking operations, located at 716 New Brunswick Avenue, Alpha, New Jersey, our investigator documented deviations from current Good Manufacturing Practices (cGMP) for Finished Pharmaceuticals (Title 21, Code of Federal Regulations, Part 211).

These deviations cause your drug product, Oxygen USP, to be misbranded and adulterated within the meaning of Section 503 (b)(4)(A), 502(b)(2), and 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

These deviations included:

1. Failure to label your drug product, at a minimum, with an "Rx only" statement, as required by law.
2. Failure to label your drug product with an accurate statement of the quantity of contents, as required by law.
3. Failure to adequately calibrate the Servomex 570A Oxygen Analyzer according to the manufacturer's directions. Specifically, you failed to calibrate this equipment with the required oxygen and nitrogen gases. It should also be noted that it is your responsibility to implement any and all calibration procedural changes that are recommended by the equipment manufacturer.

4. Failure to establish an on going training program which provides employees with training in current Good Manufacturing Practices (cGMPs). It is your responsibility to assure that all personnel who are performing and/or overseeing oxygen transfilling operations are appropriately trained.

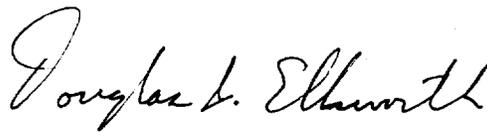
The above deviations are not intended to be an all-inclusive list of violations. As a repacker of drug products for human use, you are responsible for assuring that your overall operation and the product you distribute are in compliance with the Act and the regulations promulgated under it.

You should take prompt action to correct the above violations. 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 violations and prevent recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to the Food and Drug Administration, New Jersey District Office, 10 Waterview Blvd., Floor 3, Parsippany, New Jersey 07054, Attention: Christine M. Marmara, Acting Compliance Officer.

Sincerely yours,



Douglas I. Ellsworth
District Director