



November 25, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Douglas L. Wilkinson
President
Plaza-Wilson DME Inc.
204 South Main Street
Swainsboro, Georgia 30401

WARNING LETTER

Dear Mr. Wilkinson:

An inspection of your medical oxygen transfilling facility was conducted on November 8, 1996, by Investigators B. Douglas Brogden and Jackie M. Douglas. Our investigators documented numerous significant deviations from the Current Good Manufacturing Practice Regulations (GMPs) as set forth in Title 21 of the Code of Federal Regulations (21 CFR), Part 211. These deviations cause your transfilled drug product, Oxygen USP, to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal, Food, Drug and Cosmetic Act (the Act).

You have failed to assure that all compressed medical oxygen transfilled and distributed by your facility conforms to appropriate final specifications, to include identity and purity, prior to release. Although the H cylinders used for transfilling are labeled as Oxygen USP, you could provide no other assurance as to the purity or suitability of these drug products. You could provide no analytical test results for any of the H cylinders utilized for transfilling. No Certificate of Analysis had been received for any incoming H cylinder. In addition, you have conducted no purity or identity testing on any of the cylinders transfilled at your facility for at least two years. You did not have the capability to appropriately test transfilled cylinders. The only analyzer at your facility was a hand held analyzer which lacked the required sensitivity.

You have failed to ensure that each person engaged in the manufacture, processing and transfilling of this drug product, and each person responsible for supervising these activities, has the education, training, and experience to enable that person to perform their assigned functions in such a manner as to provide assurance that your drug product has the quality and purity that it purports or is represented to possess. This training must be in the particular operations that the employee performs and include current good manufacturing practice as it relates to the employee's functions. In fact no one at the firm had received training commensurate with their responsibilities.

This lack of training was exemplified by your firm's total lack of compliance with the applicable regulations for the transfilling of Oxygen USP. You were not familiar with the appropriate quality control steps required for transfilling and no such checks were conducted. No prefill checks were conducted on cylinders prior to filling. No suitability checks were conducted on cylinders prior to filling such as a check of the hydrostatic test dates. Nine of the E cylinders on hand bore expired hydrostatic test dates ranging from August 1983 to November 1991. Cylinders were not evacuated prior to filling and your firm lacked the necessary equipment to evacuate cylinders.

You had failed to establish formalized written procedures to cover any of the various aspects of the transfilling operation. None of the required production records were maintained to document each significant step in the transfilling of this drug product. No records were available of the number of cylinders filled, the parent lot of oxygen used, the dates cylinders were transfilled, or any lot numbers utilized by your firm. The only procedures available were Operating Instructions provided by ~~XXXXXXXXXXXX~~ with your transfilling equipment. It was not readily apparent that these procedures had been read by responsible individuals at your facility. The introduction to these instructions discusses the additional testing and records required by FDA for the packaging of this drug product.

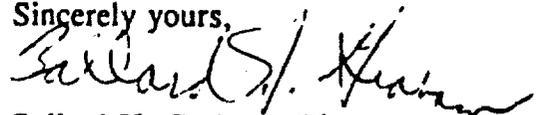
In addition, your product is misbranded in accordance with Section 502(o) of the Act, in that the drug was transfilled in an establishment not duly registered under Section 510 and the drug has not been listed as required by Section 510(j). You were provided registration and listing forms by the investigators.

At the conclusion of the inspection, Investigators' Douglas and Brogden issued their Inspectional Observations (FDA 483) to and discussed their findings with you. Neither the above discussion of deficiencies, nor the FDA 483, should be construed as an all inclusive list of violations that may be in existence at your firm. It is your responsibility to ensure that all requirements of the Act are being met at this facility and any other similar operation under your authority.

You should take immediate action to correct these violations. Failure to promptly correct these deviations may result in legal sanctions provided by the law such as product seizure and/or injunction, without further notice to you. Federal agencies are advised of the issuance of all warning letters involving drugs so that they may take this information into account when considering the award of contracts.

You are requested to notify this office within fifteen (15) days of receipt of this letter of all steps you have taken, or intend to take, to correct these violations. Your response should address any proposed actions regarding any oxygen cylinders currently in distribution which have not been properly tested and any determination on whether you plan to continue transfilling. We acknowledge your decision to voluntarily cease transfilling operations until you can bring your firm into compliance. Your response should be addressed to Philip S. Campbell, Compliance Officer, at the address noted in the letterhead.

Sincerely yours,



Ballard H. Graham, Director
Atlanta District