



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Atlanta District Office

HFI-35

60 8th Street, N.E.
Atlanta, Georgia 30309

November 14, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

James W. Rogers, Manager
Middle Georgia Medical Supply
102 Medical Center Drive
Eastman, Georgia 31023

WARNING LETTER

Dear Mr. Rogers:

An inspection of your medical oxygen transfilling facility was conducted on October 25-28, 1996, by Investigator Robert P. Neligan. Investigator Neligan documented several 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 purity, prior to release. A review of the production/transfill records revealed over 200 transfilled cylinders of medical oxygen which were released with an oxygen purity assay of 97% or below. Some of these records indicated purity results as low as 92.4%. Many of these transfill records lacked any record of a purity assay for the cylinders released. Investigator Neligan was informed that all of these cylinders had been distributed to patients.

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. Your transfilled medical oxygen does not have the purity that it purports to have or is required for such medical use. Oxygen USP must contain no less than 99.0% of Oxygen. There was no indication that anyone in a responsible position at your firm understood the significance of these deficient assay results.

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.

This lack of training was exemplified by your firm's method of calibration of the [REDACTED] analyzer and the inability to calibrate the analyzer during the inspection. No attempt is made to calibrate the analyzer in the manner or with the frequency suggested by the analyzer manufacturer. An attempt to calibrate the analyzer is made once a week as opposed to each day of use. There were also no calibration standards in use during these weekly calibrations.

In addition, the homemade label placed on your drug product is woefully inadequate." Your medical gas product is misbranded within the meaning of Section 502(f)(1) of the Act. Oxygen USP is a prescription drug and your label fails to bear adequate directions for use in accordance with 21 CFR 201.100(c). The requirement of 201.100 would be satisfied if your labeling met the requirements described in the Federal Register of March 16, 1972, (37 FR 5504) entitled "Oxygen and Its Delivery Systems, Proposed Statement of Policy". A copy of this policy is enclosed.

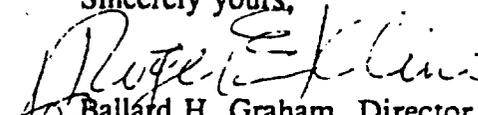
In addition, your product is misbranded in accordance with Section 502(b)(2) of the Act, in that its labeling fails to contain a statement of the quantity of the contents. Your product is also misbranded in accordance with Section 502(g) of the Act, in that its labeling fails to indicate if the oxygen has been produced by the air-liquefaction process.

At the conclusion of the inspection, Investigator Neligan issued his Inspectional Observations (FDA 483) to and discussed his 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 the numerous oxygen cylinders currently in distribution which have not been properly tested. 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

Enclosure