



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Atlanta District Office

d1579b

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

December 2, 1996

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

David P. Crowson, President
Montgomery Medical Equipment
103 South Fulton St.
P.O. Box 884
Mt. Vernon, GA 30445

WARNING LETTER

Dear Mr. Crowson:

During an inspection of your firm located in Mt. Vernon, GA on October 30 - 31, 1996, the investigator determined that your firm transfills high pressure aluminum cylinders with Oxygen USP. The Oxygen USP is a drug as defined by Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The inspection revealed that the Oxygen USP is adulterated within the meaning of Section 501(a)(2)(B) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, processing, packing, or holding are not in conformance with the Good Manufacturing Practice (GMP) for Finished Pharmaceuticals, as specified in Title 21, Code of Federal Regulations, (CFR) Parts 210 and 211, as follows:

- Failure to have written operating procedures for the following:
 1. testing and approval/rejection of components;
 2. calibration of manufacturing/testing equipment;
 3. training of employees manufacturing Oxygen U.S.P. (filling cylinders);
 4. approval/rejection of containers (cylinders - during pre-filling, filling, and post-filling);
 5. labeling of cylinders and control of labels;
 6. testing of filled cylinders prior to distribution.

- Failure to provide/document training to employees filling Oxygen U.S.P. cylinders.

You are requested to notify this office in writing within fifteen (15) days of receipt of this letter, of all steps you have taken, or intend to take, to correct these violations. Your written response should be addressed to the attention of John J. McCall, Compliance Officer, at the address in the letterhead.

Sincerely yours,

for Roger E. Kline
Ballard H. Graham, Director
Atlanta District