



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

D1199B

**PURGED**

Food and Drug Administration  
Minneapolis District  
240 Hennepin Avenue  
Minneapolis MN 55401-1999  
Telephone: 612-334-4100

cc: S HFI-35/FOI Staff  
DWA

February 18, 1997

WARNING LETTER

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Refer to MIN 97-34

Fred Slunecka  
CEO  
McKenna Hospital  
1016 South Cliff Avenue  
Sioux Falls, South Dakota 57104

Dear Mr. Slunecka:

On January 30 and 31, 1997, the Food and Drug Administration conducted an inspection of your Oxygen USP transfilling firm, Mersco Medical, Inc., at 712 South Cliff Avenue, Sioux Falls, SD. The Investigator found your firm to be operating under significant deviations from Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211 (21 CFR 210 and 211)].

Oxygen USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Medical gases transfilled by your Mersco Medical facility are misbranded within the meaning of Section 503(b)(4) in that labeling of the article, Oxygen USP, fails to bear the statement "Caution, Federal law prohibits dispensing without a prescription."

Your medical gases are also adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing,

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packaging or holding of the product are not in conformance with 21 CFR 210 and 211. Violations encountered during the FDA inspection include, but are not limited to, the following:

1. Failure to have written procedures for performing post-fill operations and recording the purity and identity of the gas and performing the post-fill leak test. Also, failure to maintain records of laboratory instruments, apparatus, gauges, and recording devices.
2. Failure to document significant manufacturing steps including: pre-fill cylinder checks, temperature and pressure checks while filling, post-fill ID and purity checks, filled leak tests, and application of proper lot number labeling.
3. Failure to perform and document review of records by a responsible person.
4. Failure to document calibration of the pressure gauge, vacuum gauge, and thermometer used in the filling operation.
5. Failure to document that each person engaged in the transfilling of medical gases has the education, training, and experience to enable that person to perform the assigned function.

This letter is not meant to be all-inclusive. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Failure to do so may result in enforcement action without further notice. This includes seizure and/or injunction.

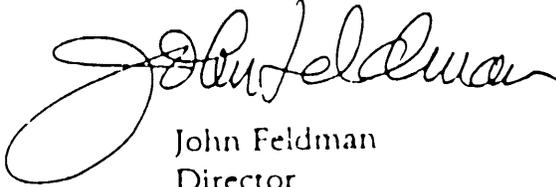
We request that you advise us in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within the requested time-frame, you must promptly inform this office of the reason for the delay and the time when each violation will be corrected.

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Your reply should be addressed to Acting Compliance Officer Rodney L. Bong at the address indicated on the letterhead.

Sincerely yours,



John Feldman  
Director  
Minneapolis District

RLB/ecf

xc: Ms. Mary C. Miller  
Manager  
Mersco Medical, Inc.  
712 South Cliff Ave.  
Sioux Falls, SD 57104